

EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US INC., et al.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC., et al.,

Defendants.

Civil Action No. 13-4158 (MLC)(LHG)

**ORDER DENYING DEFENDANTS'
MOTION FOR LEAVE TO AMEND
INVALIDITY CONTENTIONS**

THIS MATTER comes before the Court by way of a letter submitted on March 17, 2014 from Defendants Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively, "Mylan" or "Defendants"), seeking leave to amend their Invalidity Contentions ("Mylan Req."). Defendants' request was opposed by Plaintiffs Aptalis Pharma US Inc. and Aptalis Pharma Canada Inc. (collectively, "Aptalis" or "Plaintiffs") in their letter of March 25, 2014 ("Opp."). Defendants replied on April 2, 2014 ("Reply"). Plaintiffs filed a sur-reply on April 7, 2014 ("Sur-reply"). The Court has considered the parties' papers without oral argument, pursuant to FED. R. CIV. P. 78. For the reasons set forth below, Defendants' Request is DENIED.

I. BACKGROUND

The facts assume the parties' familiarity with the case and therefore are limited to those pertinent to this motion.

Aptalis sued Mylan on July 5, 2013 for infringement of U.S. Patent Nos. 8,217,083 and 8,436,051, based upon Mylan's submission of an Abbreviated New Drug Application

(“ANDA”), seeking to market and sell a product that is bioequivalent to Plaintiffs’ CANASA® product. [Docket Entry No. 1]. On November 6, 2013, Aptalis amended its Complaint to add claims for infringement of a third patent, U.S. Patent No. 7,541,384. [Docket Entry No. 25].

The Court conducted an Initial Scheduling Conference on November 1, 2013. At that conference, counsel informed the Court that because Mylan’s ANDA submission predicated the listing of the patents in the FDA’s Orange Book, this case would not have the benefit of the 30-month stay on Mylan’s ANDA approval that is customarily imposed by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iii). In other words, as the case stands now, the FDA is free to approve Mylan’s ANDA at its discretion irrespective of Aptalis’s extant infringement claims, and Mylan is free to launch its product at risk as soon as it receives that approval. In view of these pressing circumstances, the Court set an aggressive pretrial schedule for this case.

Under the schedule, Mylan served its Invalidity Contentions on Aptalis on November 22, 2013. In return, Aptalis served Mylan with its Infringement Contentions and its Response to Mylan’s Invalidity Contentions on January 8, 2014. The parties proceeded to exchange their preliminary claim constructions on January 31, 2014 and their supporting claim construction evidence on February 12, 2014. On March 5, 2014, the parties filed their Joint Claim Construction and Pre-Hearing Statement. On May 2, 2014, Mylan filed its opening Markman Brief. The Markman hearing scheduled before the Honorable Mary L. Cooper, U.S.D.J., for June 11, 2014, has been temporarily suspended pending the outcome of a discovery dispute.

II. LEGAL STANDARD

The District’s Local Patent Rules were adopted to further the “goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate

their cases.”¹ *King Pharms., Inc. et al., v. Sandoz, Inc.*, Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010)(quoting *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F.Supp.2d 819, 822 (E.D. Tex. 2007)). The rules are designed specifically to “require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed.” *Atmel Corp. v. Info. Storage Devices, Inc.*, Civ. No. 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov.5, 1998). This is “to ‘prevent the ‘shifting sands’ approach to claim construction.’ ” *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1364 (Fed.Cir.2006) (citing *Atmel*, 1998 WL 775115, at *2). As distinguished from the liberal standard for amending pleadings under Rule 15, “the philosophy behind amending claim charts is decidedly conservative.” *Atmel*, 1998 WL 775115, at *2. However, Rule 3.7 “is not a straitjacket into which litigants are locked from the moment their contentions are served”; instead, “a modest degree of flexibility [exists], at least near the outset.” *Comcast Cable Communs. Corp. v. Finisar Corp.*, Civ. No. 06-4206, 2007 WL716131, at *2 (N.D. Cal. March 2, 2007).

Pursuant to L. Pat. R. 3.7, leave to amend invalidity contentions may be granted “only by order of the Court upon a *timely* application and showing of *good cause*.” (emphases added). Rule 3.7 provides a nonexhaustive list of circumstances that may support a finding of good cause, absent undue prejudice to the adverse party,:

- (a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; (d) disclosure of an infringement contention by a Hatch–Waxman Act party asserting infringement

¹ The Court’s decision is informed by districts with analogous local patent rules, such as the Northern District of California and the Eastern District of Texas.

under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated; and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines.

L. Pat. R. 3.7. Good cause “considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted.” *Acer, Inc. v. Tech. Prob. Ltd.*, Civ. Nos. 08-877, 08-882, 08-5398, WL 3618687, at *3 (N.D. Cal. Sept. 10, 2010) (citing *O2 Micro*, 467 F.3d 1355, 1355).

The Court may only consider prejudice to the non-moving party, however, if the moving party is able to demonstrate diligence. *AstraZeneca AB v. Dr. Reddy's Laboratories Inc.*, Civ. No. 11-2317, 2013 WL 1145359, at *3 (D.N.J. 2013)(citing *Apple v. Samsung*, Civ. No. 11-1846, 2012 WL 1067548, at *2 (N.D. Cal. Mar. 27, 2012)). Courts have understood diligence to require a “showing that the party seeking leave to amend acted . . . promptly [in] moving to amend when new evidence is revealed in discovery.” *O2 Micro*, 467 F.3d at 1363. This requirement is consistent with L. Pat. Rule 3.7’s requirement that the motion be “timely.” As with good cause in general, the burden “is on the movant to establish diligence rather than on the opposing party to establish lack of diligence.” *O2 Micro*, 467 F.3d at 1366.

In determining whether good cause exists, courts have also considered such other factors as (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. See *Oy Ajat, Ltd. v. Vatech Am., Inc.*, Civ. No. 10-4875, 2012 WL 1067900, at *20–21 (D.N.J. Mar. 29, 2012) (collecting cases).

III. PARTIES' ARGUMENTS

A. Mylan's Position

Mylan seeks leave to amend its Invalidity Contentions to include indefiniteness arguments based on the use of the term “about” in several of the asserted claims. It argues that its amendment is needed because Aptalis recently adopted a claim construction position that interprets “about” as “approximately,” a position which Aptalis only revealed during the parties’ exchange of their respective preliminary claim constructions on January 31, 2014. Mylan Req. at 5. Mylan did not foresee this development:

When Mylan initially drafted its invalidity contentions, it had no expectation that Aptalis would propose an interpretation that inherently allows unlimited variability, rendering the claim indefinite, nor could it have anticipated amending its Invalidity Contentions any earlier than the time Aptalis served its proposed preliminary constructions.

Id. Mylan faults Aptalis for failing to advance its construction, or any construction, as part of its Infringement Contentions. *Id.* Therein, Aptalis did not construe “about,” but merely parroted the language of the claims, without interpretation, and then copied portions of Mylan’s ANDA below the parroted claim language. *Id.*

Mylan claims diligence in its efforts to address the new issue. It timely sought Aptalis’s consent to an amendment to its Contentions, but after over a week of negotiation attempts, Aptalis refused. Mylan was left with no choice but to file the instant application. *Id.*

In parallel, Mylan asserts that its proposed amendment is exercising a right it expressly reserved for itself in its original Invalidity Contentions. *Id.* Therein, Mylan states that it “reserves the right to supplement, amend and/or modify these contentions at any time” based

upon a number of reasons, including “relevant positions on claim construction or infringement taken by Aptalis.” Mylan Req., Exhibit B, at 2.

With regard to prejudice, Mylan argues that its request to amend its contentions was made in the early stage of this case, before claim construction or fact discovery were completed and therefore any impact on the case is reduced. *Id.* at 6. It also argues that denial of its request would prejudice it greatly, affecting both its invalidity case and its claim construction position. *Id.* at 7. The amendments it proposes are not burdensome because it is not raising a new theory of invalidity, but merely expanding on theories of indefiniteness it has already advanced and Aptalis does not need to expend significant resources to modify its position,. *Id.* at 7-8. Moreover, Aptalis should not be prejudiced by this amendment because it has been on notice of Mylan’s theories of indefiniteness since November 2013 and Sandoz has raised indefiniteness defenses in Aptalis’s parallel case against Sandoz, 13-cv-4290. *Id.* at 8 (citing Joint Claim Construction and Prehearing Statement filed in 13-cv-4290 at 8-9, 11-12). Finally, should its request be granted, Mylan believes no adjustment to the Court’s schedule would be needed. *Id.*

B. Aptalis’s Position

Aptalis opposes Mylan’s request on the grounds of good cause and prejudice. With respect to good cause, Aptalis points to Mylan’s own Paragraph IV certification letters as evidence that Mylan has been analyzing the patents in suit since at least October 2012. Opp. at 3. In view of the amount of time Mylan has been studying the patents, and the fact that every asserted claim recites “about” either directly or through dependence on a claim that does, Aptalis is skeptical of Mylan’s purported diligence given its failure to raise its current indefiniteness argument until now. Aptalis questions how Mylan came to specifically address “about” in its non-infringement arguments, but overlooked it in its invalidity position. *Id.* at 3-4. Aptalis cites

the Local Patent Rules as well, arguing that it was Mylan’s duty to consider whether the plain and ordinary meaning of any of the asserted claim terms supports an indefiniteness argument. *Id.* at 4. Here, not only is Aptalis’s construction of “about” its plain and ordinary meaning, it is consistent with established case law from both the Court of Appeals for the Federal Circuit and this District. *Id.* (citing cases which interpret “approximately” as the plain and ordinary meaning of “about”).

Aptalis characterizes Mylan’s reliance on Aptalis’s recent claim construction position as a trumped up excuse. Based on timing, Aptalis posits that Mylan cannot logically claim that its need to amend its contentions was prompted by information in Aptalis’s preliminary claim construction served on January 31, 2014, because Mylan itself raised this very indefiniteness argument in papers it supplied at the same time it received Aptalis’s constructions. *Id.* at 5. In fact, Aptalis claims that Mylan has since admitted during the meet and confer process that its new indefiniteness arguments are entirely independent of Aptalis’s construction of “about.” *Id.* at 6. Aptalis’s view is that Mylan either simply failed to recognize its indefiniteness argument or intentionally omitted it from its original contentions, and that neither circumstance demonstrates the diligence required for good cause. *Id.*

Aptalis argues that Mylan’s lack of good cause is a sufficient basis to deny its motion. *Id.* Nevertheless, Aptalis asserts that the prejudice Mylan’s amendment would wreak upon both Aptalis and the Court provides a further basis for denial. *Id.* Mylan’s changes would expand the case by introducing a new invalidity argument to every asserted claim, in five different contexts. *Id.* To respond, Aptalis would need both time and resources to reevaluate work it has completed over the past several months. *Id.* It would require revisiting its responses to Mylan’s invalidity contentions, its infringement contentions, and its claim construction position. As a practical

matter, it might force Aptalis to reconsider positions it has taken in a parallel suit against Sandoz.

Id.

IV. ANALYSIS

A. Timing and Good Cause

Mylan filed its motion on March 17, 2014 and alleges that it did not appreciate its need to amend until just two weeks earlier. For the purpose of assessing its timeliness, the Court sees no reason to reject Mylan's representation. Accordingly, the Court finds that Mylan's motion was timely filed.

The Court's inquiry into Mylan's diligence is more searching. Mylan has not explained why it was unable to muster its indefiniteness argument as to "about" more than four months earlier, when it was required to do so under the Local Patent Rules. Mylan endeavors instead to lay the blame at Aptalis's feet for failing to advance Aptalis's claim construction for "about" until now, or to even signal it as part of its infringement contentions. These positions are inconsistent with the District's Local Patent Rules, the Pretrial Scheduling Order for this case, and the settled case law of indefiniteness.

1. Local Patent Rules 3.3 and 3.6, and FRCP 16

Under the Local Patent Rules and this Court's Scheduling Order, Mylan was not entitled to receive Aptalis's claim construction prior to framing its indefiniteness position. Local Patent Rule 3.6 prescribes the orderly exchange of contentions and their supporting information for Hatch-Waxman cases. The Rule requires an ANDA applicant to disclose its Invalidity Contentions fourteen days after the Initial Conference. Loc. R. 3.6(c). Under Rule 3.6, those

contentions must contain the disclosures required under Rule 3.3, which include “[a]ny grounds of invalidity based on . . . indefiniteness under 35 U.S.C. § 112(2).” Loc. R. 3.3(d).

Consistent with these Local Patent Rules, pursuant to Federal Rule of Civil Procedure 16, and in consultation with counsel for both parties at the Initial Conference, the Court issued a Pretrial Scheduling Order granting Mylan 21 days, an expansion of the 14 days ordinarily provided under the Local Patent Rule, to serve its Invalidity Contentions on November 22, 2013. [Docket Entry No. 31]. The Order also set a deadline of January 8, 2014 for Aptalis to serve its Infringement Contentions and a deadline for the parties to simultaneously exchange preliminary proposed claim constructions on January 31, 2014. Thus, from the outset of this litigation, Mylan was on notice that it was expected to prepare and serve its Invalidity Contentions before it received Aptalis’s Infringement Contentions or Aptalis’s preliminary claim constructions.

By the time Mylan was preparing its Invalidity Contentions, it had studied the patents, their prosecution histories, and the prior art it had uncovered to date. *See, e.g.,* Notice of Paragraph IV Certification Regarding U.S. Patent No. 8,217,083, Opp. Exhibit B. It had also received Aptalis’s disclosure of asserted claims, each of which recites the term “about” either directly or indirectly. As Mylan admits, Aptalis’s disclosure copied, word-for-word, the language of the asserted claims and also cited Mylan’s ANDA. Thus, Mylan’s most direct evidence as to what the claims mean, at the time it prepared its contentions, was the claims themselves as issued by the U.S. Patent Office and repeated by Aptalis. Still, Mylan urges that it could not have anticipated that Aptalis might take the position that “about” means “approximately.” According to Mylan, both the plain and ordinary meaning of “about” and “approximately” suffer from the same defect of failing to provide objective limits as to the range encompassed by the term. Mylan Req. at 6 (“Because the claim elements that include the word

‘about’ are close to the prior art, not construing the term ‘about’—or giving the term its plain and ordinary meaning—would leave Mylan—and any other alleged infringer—without knowledge as to where the bounds of the claims fall.”) This argument only crystallizes the weakness of Mylan’s position insofar as it concedes that Mylan did not anticipate that Aptalis might adopt a plain and ordinary meaning of “about.” Had it, Mylan presumably would have perceived its need to raise the indefiniteness arguments it seeks leave to add now.

Without a persuasive explanation, it is difficult for the Court to ascribe diligence to an ANDA applicant who fails to foresee that a patentee might rely on the plain and ordinary meaning of its claim terms. As movant, Mylan has the burden of establishing its diligence. Its claim that it *was* surprised does not suffice. It is Mylan’s task to explain the how and why of its surprise, the reasons why a diligent inquiry would not have discovered the grounds for the contentions it seeks to add now. Mylan has not carried this burden.

2. Indefiniteness under 35 U.S.C. § 112, Paragraph 2.

Mylan argues that its indefiniteness position was prompted by Aptalis’s claim construction of “about,” but has cited no authority for a connection between the two, nor has this Court found one. Section 35 U.S.C. § 112 was amended effective 2012. The version of the statute applicable to this case requires that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 ¶2 (2011). The United States Supreme Court recently restated, unanimously, the considerations pertinent to a § 112, ¶2 inquiry. “First, definiteness is to be evaluated from the perspective of someone skilled in the relevant art.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2128 (2014) (citations omitted). “Second, in assessing definiteness, claims are to be read in light of the patent’s specification and prosecution history.

Id. “Third, definiteness is measured from the viewpoint of a person skilled in the art at the time the patent was filed.” *Id.* at 4 (interior quotation marks omitted). Overall, the Supreme Court has interpreted Section 112, ¶2 “to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Id.* at 2129. Mylan has advanced no authority to support its assertion that its substantive consideration of definiteness requires a patentee’s claim construction and the Court has located none. Accordingly, the Court finds Mylan’s argument unpersuasive.

As a practical matter, Mylan may have preferred to craft its validity arguments after careful study of Aptalis’s positions with respect to both infringement and claim construction. Strategically, there are any number of advantages to be gleaned from pinpointing the weaknesses of a patentee’s litigation positions. The Local Rules, however, require Mylan to speak first, and the substantive patent law and factual record indicate it had the information it needed. That Mylan preferred a better strategic position is not sufficient.

B. Prejudice

Because the Court finds that Mylan failed to act with diligence, it need not consider prejudice at all. *O2 Micro*, 467 F.3d at 1368; *AstraZeneca AB*, 2013 WL 1145359, at *5; *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civ. No. 10-6108, 2012 WL 3133943, at *8 (D.N.J. July 30, 2012); *Apple*, 2012 WL 1067548, at *14; *Acer Inc.*, 2010 WL 3618687, at *5. Nevertheless, even if the Court were to consider prejudice, that factor would weight in favor of Aptalis as well.

In deciding whether Mylan’s proposed amendments would unfairly prejudice Aptalis, the Court considers whether permitting the proposed amendments would (1) require Aptalis to

expend significant additional resources; or (2) significantly delay the resolution of the dispute.

TFH Publications Inc. v. Doskocil Mfg. Co., Inc., 705 F.Supp.2d 361, 366 (D.N.J.2010); *see also O2 Micro*, 467 F.3d at 1366–68.

Mylan’s proposed Amended Invalidity Contentions would expand its “about” indefiniteness arguments in a section that spans four pages. *Id.* at 41-44. By its own admission, Mylan’s arguments implicate claim elements as to five separate features—drug load, release rate, drug dose, tap density, and surface area—which are recited in approximately 30 asserted claims. At a minimum, it would impose a burden of responding to the new contentions. As a practical matter, Aptalis cautions that the change would require it to revisit its infringement position, its claim construction position, and its validity positions with respect to prior art. Mylan’s claim that it put Aptalis on notice of its indefiniteness theories in a general way is not sufficient.

Whether a claim meets the definiteness requirement of § 112 ¶2 is a fact-specific and term-specific analysis, requiring particulars that Mylan did not provide. Mylan’s attempts to bolster its case by citing Sandoz’s arguments in the parallel suit between Aptalis and Sandoz is unavailing for the same reason. The Court has reviewed the Joint Claim Construction and Prehearing Statement in that case and it finds that Sandoz statements also lack the particulars that might be expected to put Aptalis on specific notice that the term “about” is indefinite.

Mylan has not met its burden of establishing that granting its motion would not significantly delay resolution of the case. In light of the above, and given this case’s tight schedule and the fact that there is no 30-month stay in place, the Court finds that allowing the amendment would work a prejudice on Aptalis.

V. CONCLUSION

For the foregoing reasons, and for good cause shown,

IT IS on this **20th** day of **June, 2014**,

ORDERED that Mylan's Motion to Amend its Invalidity Contentions is hereby
DENIED.



LOIS H. GOODMAN
United States Magistrate Judge

EXHIBIT 2

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BRISTOL-MYERS SQUIBB CO.,

Plaintiff,

v.

APOTEX, INC., et al.,

Defendants.

Civil Action No. 10-5810 (MLC)

ORDER

This matter comes before the Court by way of the January 28, 2013 application by Defendants Apotex, Inc. and Apotex Corp. (hereinafter referred to collectively as “Apotex”), seeking leave to amend their Non-Infringement Contentions and Invalidity Contentions. Docket Entry No. 107 (hereinafter “Application”). Plaintiff, Bristol-Myer Squibb, Inc. (“BMS”), filed a lengthy objection to the amendments on February 6, 2013. Docket Entry No. 112 (hereinafter “Opposition”). Apotex submitted a reply on February 8, 2013. Docket Entry No. 115 (hereinafter “Reply”).

The Court considers the application on the papers, pursuant to Fed. R. Civ. P. 78.1(b). Because this decision is intended for the parties only, and because the entire record on the application is subject to motions to seal, the Court refers to certain arguments and factual assertions but has not set them out herein, given the Court’s intention that this Order not be placed under seal. For the reasons stated herein, Apotex’s request for leave to amend is granted in part and denied in part.

I. Background and Procedural History

On November 8, 2010, BMS filed a Complaint against Apotex for infringement of four patents which cover BMS’s Sprycel (dasatinib) pharmaceutical drug product after Apotex filed

an Abbreviated New Drug Application with the Federal Drug Administration (“FDA”). *See* Complaint at Docket Entry No. 1. The four patents at issue are: U.S. Patent No. 7,491,725 (the “‘725” patent), U.S. Patent No. 7,152,856 (the “‘856” patent), U.S. Patent No. 7,125,875 (the “‘875” patent), and U.S. Patent No. 6,596,746 (the “‘746” patent). The ‘746 patent covers, among other things, the active drug ingredient, the dasatinib compound. The ‘856 and ‘875 patents cover the methods of using dasatinib to treat cancer. The ‘725 patent claims a particular crystalline form of dasatinib. As this is a patent infringement case under the Hatch-Waxman Act, a 30-month stay of FDA approval is in place, set to run on December 28, 2013.

The Court conducted an initial scheduling conference on April 12, 2011. At the conference, the Court stressed the importance of adhering to the schedule in light of the 30-month stay, and in fact tightened the schedule proposed by the parties in the Joint Discovery Plan. Ultimately, the Court set a schedule, memorialized in an Order dated May 6, 2011. Docket Entry No. 20. According to the May 6 schedule, Apotex was to, and did, serve its Invalidity and Non-Infringement Contentions by July 5, 2011. *See id.*; Opposition at 3.¹ Pursuant to an amended scheduling order, Docket Entry No. 34, BMS filed its Responses to Apotex’s Invalidity and Non-Infringement Contentions on October 7, 2011. Opposition at 3. On November 29, 2011, the instant case was consolidated with *Bristol-Myer Squibb v. Apotex, Inc., et al.*, Docket 11-6918, as the cases were between the same parties and with regard to the same patents, but related to a new and separate ANDA filed by Apotex for different dosages of the underlying product. The schedule was amended again and a new Order, dated December 14, 2011 was entered at Docket Entry No. 44. Pursuant to the December 14 Order, Apotex

¹ Due to the differences of pagination between the parties’ papers and ECF, especially with regard to the pagination of the voluminous exhibits, all page references herein to documents filed on the docket will be by ECF pagination, not by the page number that appears on the page of the brief or exhibit itself.

supplemented its Non-Infringement and Invalidity Contentions by January 20, 2012. BMS supplemented its Infringement and Validity Contentions by February 10, 2012.

The December 14 schedule also set forth the timing of the claim construction process, which was extended at the request of the parties. *See Docket Entry No. 52 & 59.* In accordance with the amended schedule, the parties completed their *Markman* submissions, and the Court held the *Markman* hearing on September 10, 2012 and October 2, 2012. On September 11, 2012, the day after the hearing, the parties sought and received an additional extension of the schedule, which provided for fact discovery to close on January 11, 2013;² opening expert reports to be served by February 15, 2013; responsive expert reports to be served by March 15, 2013; reply expert reports by April 5, 2013; and the close of expert discovery by May 3, 2013. The Court also set a schedule by which dispositive motions are to be filed in May, 2013 on an extended briefing schedule at the parties' request. The Final Pretrial Conference is scheduled for August 2, 2013. The September 11 Order also provides that trial will begin on September 24, 2013, or as soon thereafter as the Court's schedule allows.

On January 28, 2013, Apotex filed the instant application for leave to amend its Invalidity and Non-Infringement Contentions. Docket Entry No. 107. Generally speaking, Apotex seeks to make several amendments, adding references to recently taken depositions of BMS witnesses and new prior art, and either adding new theories or supplementing existing ones relating to invalidity and non-infringement.³ Given the fact that this case is on such a tight schedule, the Court requested that BMS submit its response by February 1, 2013. When BMS requested an additional week, the Court convened a conference call on January 31, 2013 to address

² A short extension of fact discovery for the completion of depositions was granted due to scheduling conflicts of the witnesses and parties. *See Docket Entry No. 102.* All other discovery was to be completed by January 11, 2013.

³ The Court notes that there is no definitive list of categories or types of amendments Apotex seeks to make. The parties rarely agree in their submissions, and in fact each submitted wholly incompatible charts, disagreeing as to whether Apotex merely seeks to add support for a pre-existing theory or adds entirely new theories.

scheduling. During the call, BMS expressed great concern with the scope, volume and timing of the proposed amendments. Because of the upcoming expert discovery, the undersigned stressed the importance of resolving this issue promptly so as not to impact the schedule, and urged BMS to respond as quickly as possible. After some discussion, BMS proposed making its submission by February 6, 2013, to which the Court agreed. Apotex did not object to the schedule, nor did it request that the schedule include a date for it to reply. Indeed, throughout the call, Apotex never suggested that it intended to reply.

Based on the schedule set for BMS's response, the Court set a tentative date for oral argument on February 11, 2013, with the caveat that the hearing would be canceled if, upon review of the submissions, the Court determined it could rule on the papers.

BMS filed its opposition on February 6, 2013. Docket Entry No. 112. On February 8, 2013, having made an initial review of the papers, the Court concluded that oral argument would not be necessary, and so notified counsel by text order. Later that day, Apotex filed a lengthy reply, supported by voluminous exhibits. *See* Docket Entry No. 115.

II. Analysis

a. Standard of Review

The Local Patent Rules govern the litigation process of patent infringement cases in the District of New Jersey. *See* L. Pat. R. 1.2. The Rules are "designed specifically to require parties to crystalize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Info. Storage Devices., Inc.*, 1998 WL 775115 at *2 (N.D. Cal. 1998).⁴ The Court recognizes, however, that the Rules are not a "'straightjacket

⁴ The District of New Jersey originally developed its Local Patent Rules based on those adopted by the Eastern District of Texas and the Northern District of California. While some changes have been made to the Rules since then, the original purpose and general substance of the Rules still remain closely aligned. The Court therefore finds it appropriate to look to those districts for additional guidance.

into which litigants are locked from the moment their contentions are served,’ but instead, ‘a modest degree of flexibility [exists], at least near the outset.’” *TFH Publications, Inc., v. Doskocil Manufacturing Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010), quoting *Comcast Cable Communs. Corp. v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007). Accordingly, L. Pat. R. 3.7 expressly permits a party to seek leave to amend its contentions but the party seeking leave must make a particularized showing. The Rule includes a non-exhaustive list of circumstances in which, absent undue prejudice to the non-moving party, a court may permit an amendment, including where the court announces a claim construction different from that posed by the party seeking amendment, and where material information was discovered that was not and could not have been found earlier despite a diligent search. See L. Pat. R. 3.7.

While the list is non-exhaustive, the flexibility of the court is constrained by the overarching goal of the Local Patent Rules. It is, therefore, a more conservative standard for amendments in patent cases than is required under Fed. R. Civ. P. 15, which governs amendments to pleadings in general. *AstraZeneca AB v. Hanmi USA, Inc.*, No. 11-760, 2011 WL 5526009, at * 4 (D.N.J. Nov. 14, 2011).

Under R. 3.7, the moving party must establish three factors: 1) the application was timely made; 2) the party has good cause for the application; and 3) there is no undue prejudice to the non-moving party. *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 10-6108, 2012 WL 3133943, at * 2 (D.N.J. 2012). The failure to establish any one factor may be sufficient for a denial of leave to amend. See *Nautilus Neurosciences, Inc., v. Wockhardt USA LLC*, No. 11-1997 (ES), Docket Entry No. 98, at 6, n.3 (D.N.J. Jan. 23 2013).

The requirement of a timely application is founded on the recognition that “were [the parties] not required to amend their contentions promptly after discovering new information, the

contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery in trial preparation.” *See O2 Micro Intern. Ltd. v. Monolithic Power Systems*, 476 F.3d 1355, 1366 (Fed. Cir. 2006); *Jazz Pharma.*, 2012 WL 3133943 at *5. A timely application is one in which the party moved for leave to amend at the earliest opportunity it became or could have become aware of the new information that forms the basis for the request to amend. *See Jazz Pharma.*, 2012 WL 3133943 at *5 (rejecting the defendant’s argument that a five month period to review new documents constituted diligence). Greater flexibility will be allowed with regard to an amendment sought at or near the outset of the litigation. *See TFH Publications*, 705 F. Supp. 2d at 366 (allowing the plaintiff to amend when the request was made approximately two months after the infringement contentions were initially served).

Good cause is closely aligned with the concept of a timely application, and also looks to the diligence of the party seeking the amendment. *Nautilus Neurosciences*, at 7. A showing of diligence requires more than moving quickly, it “requires diligence throughout the discovery process and that the moving party not only must act promptly upon discovery of new [information], but also must establish that it was diligent in its search.” *West v. Jewelry Innovations, Inc.*, Civil No. 07-1812, 2008 WL 4532558, at *2 (N.D. Cal., Oct 8, 2008). Courts have found good cause where parties were diligent in deciphering relevant arguments and moved quickly for leave to amend. *See AstraZeneca AB*, 2011 WL 5526009 at *6 (finding the plaintiff was diligent when it sought leave to amend its validity contentions two and a half months after receiving the new information and less than three months after the plaintiff’s original validity contentions were served). In contrast, courts have denied leave where a party unreasonably delayed seeking leave to amend once it had the information in hand. *See King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 WL 2015258 at * (D.N.J. May 20, 2010) (finding a lack

of diligence where the defendant knew of the prior art, but failed to recognize its materiality for 18 months).

Last, the court considers the prejudice to the non-moving party. *See AstraZeneca AB*, 2011 WL 5526009 at *7. Undue prejudice may be found where the non-moving party is forced to expend significant additional resources, or where the amendments would delay the resolution of the case. *Nautilus Neurosciences*, at 10. Courts may consider the relevant dates in a case, and the reliance of the parties on that schedule for the development of their respective strategies. *Jazz Pharma.*, 2012 WL 3133943 at *8.

The burden of demonstrating good cause lies with the moving party “rather than on the opposing party to establish a lack of diligence.” *Nautilus Neurosciences*, at 7-8. The burden should be met in the first instance in the moving submission. It is not for the moving party to make generalized statements of timeliness, diligence and good cause, and to leave it to the responding party to bear the burden of disproving those allegations in its opposition so that movant can make its case on reply.

The Court notes at the outset that Apotex’s moving application, which is seven pages plus attachments, makes generalized and sometimes conclusory statements with regard to timeliness, good cause and the lack of prejudice. *See Docket Entry No. 107*. A single paragraph is devoted to timeliness, essentially arguing that any delay is BMS’s fault due to its belated document production. Nowhere does Apotex tie that belated production to its proposed amendments. Docket Entry 107 at 3.

Apotex attempts to close many of these gaps in its reply brief, which really sets forth the heart of Apotex’s argument. Because of the importance of the issues raised, the Court has

considered the reply, even though Apotex did not seek to include it as part of the briefing schedule set during the January 31 conference.

b. Timeliness of the Application

Apotex argues its application is timely because its proposed amendments incorporate new information that was only recently discovered and request for leave was timely sought when BMS refused to give its consent. *See Application* [Docket Entry 107]; Reply at 2. Apotex states the new evidence it cites involves:

- (1) inventor depositions from November 2012-January 2013 (information inherently non-public and not otherwise available to Apotex); (2) documents from over 2.6 million pages that BMS failed to earlier produce; (3) a court order invalidating the foreign versions of BMS's patents; and (4) additional prior art selected to rebut BMS inventor deposition testimony and/or BMS contentions that conflict with inventor depositions testimony.

Reply at 5-6. Apotex argues it made its intention to amend known to BMS on January 10, 2013,

had its proposed amendments to BMS by January 18, 2013, and sought leave of court within

days of BMS's refusal to consent. Reply at 5. Furthermore, these late revelations from the

depositions came on the heels of a generally slow and voluminous document production, a late

supplementation of interrogatory responses in January 2013, and various scheduling conflicts.

Reply at 5. Because the fault is on, or, at very least shared with, BMS, Apotex says it cannot be

held solely responsible for any delay in its request for leave to amend. Application at 3.

BMS counters that Apotex's application is not timely by any measure. BMS asserts that Apotex's claims of a late document production by BMS is a red herring, and that the information actually cited as the basis for the proposed amendments was produced and in the hands of Apotex months earlier, or was information Apotex had the capability of obtaining independently. Opposition at 32-34. BMS further states that Apotex's request for leave to amend is too late

within the schedule of a patent infringement case, as the parties were days from exchanging affirmative expert reports. Opposition at 28. At the time of the request, 18 months had already passed since Apotex served its original contentions, and more than a year since it served its supplemental contentions. Opposition at 7. During that time, BMS says it developed a strategy for the case, based upon Apotex's disclosures. BMS conducted discovery, retained experts and participated in a *Markman*. Allowing the amendments would give BMS only days to analyze and incorporate the new information, and to choose and prepare its respective experts. Opposition at 32. BMS contends it may need to retain new experts if the amendments are permitted and may have to seek another *Markman* hearing. Opposition at 23. Indeed, BMS contends that it could well need to re-evaluate its strategy for trial.

The Court can find no case in which a party has been allowed to amend its contentions at this late stage of the litigation, when the *Markman* has been conducted and all fact discovery has been completed. *See, e.g., Nautilus Neurosciences* (denying amendments sought 14 months after original contentions were exchanged, but before the *Markman* hearing had occurred); *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, 2010 WL 2015258 (D.N.J. May 20, 2010) (denying amendments where the court had ruled on claim construction and the dates for the final pretrial conference and trial had been set).

There is no question that Apotex's request for leave to amend is untimely. The parties recently began the exchange of expert reports. Dispositive motions are to be filed May 17, 2013. The Final Pretrial Conference is scheduled to be conducted on August 8, 2013. The trial is a mere seven months away, set to begin in September of this year. This schedule is already tight, in part because of the statutory framework and in part because of the various extensions sought

by the parties. There simply is no room in the schedule to grant further extensions at this late date.

Apotex argues that the lateness of its amendments is not its fault, and material information was uncovered during the final weeks of discovery. Apotex is concerned about prejudice to the presentation of its own case, and accuses BMS of “hiding the ball” until late in the discovery process, thereby preventing Apotex from fully developing its arguments. In light of these concerns, the Court will examine whether Apotex has good cause for the amendments, despite the late hour of its request.

c. Good Cause and Prejudice⁵

The burden is on Apotex to demonstrate good cause. Apotex asserts it has shown good cause for the amendments for several reasons: it sought to amend as soon as it was possible; the new evidence cited could not have been known to Apotex earlier; and the circumstances here, for example relating to “best mode” contentions, are not contemplated by the Local Patent Rules, and thus Apotex seeks to amend its contentions to combat potential arguments BMS may make. *See Reply at 5-6.* BMS argues that in many cases, Apotex had the ability, knowledge, or access to make the sought-after amendments earlier in the process. *See Opposition at 25.*

BMS provided a chart setting forth the proposed amendments and its understanding of the purpose for which each proposed amendment is to be used. *See BMS’s Chart, Opposition, Exhibit O, Docket Entry No. 112-1.* On reply, Apotex submitted its own chart. *See Apotex’s Chart, Reply, Exhibit 2, Docket Entry No. 115-4.* Notably, Apotex’s chart contains 17

⁵ Both Apotex and BMS intertwine their arguments of good cause and prejudice. Apotex argues in many instances that BMS is the cause of the late request and it would be prejudiced if the amendments were denied. BMS argues the opposite, that Apotex has failed to demonstrate good cause, and BMS would be prejudiced as a result. As both parties use prejudice and good cause as two sides of the same coin, the Court considers both factors together in determining the appropriateness of the amendments.

categories, while BMS's chart contains 82. Apotex does not explain how its chart relates to the one submitted by BMS, and it is virtually impossible to reconcile the two. The Court has therefore been forced to conduct its own in-depth and painstaking review of each of the proposed amendments in an attempt to make sense of the arguments. A brief summary of each party's argument is set forth below.

i. Apotex's Argument

Apotex seeks to amend its Non-Infringement Contentions to include citations and references regarding three theories that support its position that Apotex's ANDA product lacks stated properties of the patent claims and therefore cannot infringe. *See Reply 8-11 and Exhibit F, Docket Entry No. 107-3 at 116-17, 120-21.* Apotex largely relies on the timing of its obtaining the information relied upon for the amendments, citing to depositions taken in January, 2013 and/or the September, 2012 *Markman* hearing in support of its argument that it could not have amended sooner. *See, e.g., Reply at 8.* For example, Apotex argues that at the inventor deposition in January 2013, it learned new information regarding testing of the product for infringement purposes. *Reply at 9-10.* With regard to other proposed amendments, Apotex argues that it is entitled to amend as a preemptory move, in case BMS raises a particular defense to the new contentions and in response to BMS's "prior threat in its infringement contentions that undisclosed testing might be forthcoming in the future." *Reply at 10.*

In terms of amendments of Invalidity Contentions, Apotex seeks to add 16 new prior art references, numerous references to deposition transcripts and to WO '778, and contentions relating to indefiniteness and written description raised at the *Markman* hearing. Apotex focuses its argument largely on the lack of prejudice to BMS. *Reply 11-13.* Citing, for example, to a new reference relating to the written description theory, which Apotex contends was brought up

at the *Markman* in September 2012, Apotex argues BMS has been on notice since September that Apotex would raise this issue. Application at 3; Reply at 13-14. Apotex argues that the new prior art is support for its existing positions and merely gives BMS background as to what Apotex's experts may use to illustrate their points to the Court, without introducing anything new. Reply at 11.

Apotex seeks to add evidence, prior art, and a counterargument against BMS's potential use of a theory that the development of the subject matter of the '725 patent was "unexpected." Reply at 12. Apotex states the depositions of BMS's witnesses reflected a change in BMS's wording from its prior statements, denoting that BMS might incorporate a new theory of "unexpected results" as to which Apotex has had no notice. Accordingly, Apotex argues that it would be prejudiced if it is not permitted to amend. Reply at 12.

Apotex also seeks to amend its contentions to add a "best mode" invalidity argument. Reply at 14. Citing that the legal test "expressly evaluates subjectively what the named inventors actually knew and believed to be their best mode," Apotex argues it has good cause as it moved to amend within days of completing the inventors' depositions, which occurred from November 2012 to January 2013. Reply at 14.

Throughout its papers, Apotex gives short shrift to BMS's claims of prejudice. For example, Apotex says that its proposed amendment with regard to testing is really nothing new because BMS has long been on notice that Apotex argues that its product does not infringe. Reply at 9.

Apotex also argues that because much of the need to amend results directly from the testimony of BMS's witnesses, which Apotex argues undermines BMS's own arguments, the

only prejudice BMS would suffer is having to undo the damage done by its own witness at the recent deposition. Reply at 8-10.

Apotex also rejects the notion that BMS would need additional discovery or experts, let along another *Markman*. At most, Apotex asserts any new issues could be addressed by BMS's experts through upcoming expert reports.

ii. BMS's Argument

BMS contests that Apotex has good cause and cites substantial prejudice that it will suffer in both resources and delay of resolution should Apotex be allowed to amend. In many cases, BMS argues that Apotex fails to explain its delay in seeking to amend (or indeed for having failed to address some of the issues raised earlier in the case). According to BMS, Apotex and its experts were aware of the theories they now seek to add, or were alerted to them at very least when they were discussed in prior BMS positions. Opposition at 19 & 27. BMS also cites to instances where Apotex had or could have obtained the information, either because the information was available in the public sphere or was produced in discovery, and a late-scheduled deposition was not required to develop the theory. *See* Opposition at 27-28. In this regard, BMS argues that it was Apotex that delayed discovery, leading to the need to amend. Thus, according to BMS, the delay was the result of Apotex's own lack of diligence in the conduct of discovery. Opposition at 4-5.

The crux of BMS's opposition, however, rests on the substantial prejudice it would suffer should Apotex be allowed to amend. BMS says it relied on Apotex's disclosures, as it should under the Local Patent Rules. Opposition at 11. For almost every category of proposed amendments, BMS catalogs the substantial expenditures it would likely incur. For example, BMS argues that several of the new theories challenge terms construed or defined in the case,

and could impact claim construction and necessitate a new *Markman*. Opposition at 18, 20 & 23. For most of the proposed amendments, BMS claims it would need new fact discovery, experts, and depositions. Opposition at 18, 20, & 23. In addition, BMS asserts that the proposed amendments are so significant that it would have to reevaluate its case strategy, which it has been developing for the last year and a half. Opposition at 11. Even without a new *Markman*, BMS states that the additional work required to present defenses to Apotex's new contentions could not fit within the remaining schedule. Opposition at 18.

iii. The Court's Findings

In making the present application, the burden rests squarely on Apotex. The Court finds that Apotex has not met that burden except in a very limited circumstance, set forth below. Taken against the backdrop of the current stage of litigation, it is unclear to the Court why certain theories could not have been brought up sooner. Many of the citations and new contentions that Apotex seeks to amend are not only to the January, 2013 depositions, but also to the September 2012 *Markman* hearing. Indeed, BMS argues Apotex could have and should have raised some of these proposed amendments even before the *Markman*. Apotex provides no explanation for the 4-month delay after the *Markman*, especially given the critical timing element at play here. Apotex simply does not explain why depositions were necessary in addition to the *Markman* hearing to establish the need for each amendment. Furthermore, Apotex does not explain why these depositions did not occur earlier. Apotex originally cites to a voluminous document production, but provides no connection between the timeliness of that production of documents and the need for the proposed amendments at this late date. As such, Apotex fails to demonstrate good cause or reasonable diligence.

Apotex's papers raise at least two situations where they seek to amend to bring contentions out of an abundance of caution to proactively address theories BMS may raise in the future. Even if that were the case, the time for proactive behavior has long since passed. The Local Patent Rules are designed to make parties disclose their contentions early in the litigation. This applies to both sides – in essence, both parties live and die by what they contend. Apotex may not amend at this late stage to bring a potential theory; anticipation of a possible argument is not good cause. Apotex is not, however, left without recourse. If BMS does in fact attempt to develop a theory that goes beyond what is reasonably anticipated from its own Contentions, Apotex may seek appropriate relief from the Court.

Finally, of particular concern to the Court is prejudice to the non-moving party and to the schedule in this case. BMS claims Apotex's amendments will require substantial amounts of new discovery, expert analysis, depositions, and potentially a new *Markman*. Looking at the sheer number of new prior art references, and the number of new contentions of non-infringement and invalidity, BMS would at the very least be entitled to the opportunity to review and prepare defenses to all of this new material. BMS says it cannot do so in a vacuum. The parties are currently exchanging expert reports. The volume of the amendments alone indicates this would be impossible to incorporate under the current schedule. It is Apotex's burden to demonstrate good cause, and that good cause is balanced against the potential prejudice to the non-moving party. Here, Apotex attempts too much too late, and the Court therefore finds that to allow the amendments would be prejudicial, both in terms of resources and delay of resolution.

Apotex seeks to add references to the January 2013 depositions in support of previously stated theories. *See Reply at 11.* BMS does not object to the addition of these specific and

limited references. *See* Opposition, FN 2. Thus, Apotex may add references to the recent depositions, but limited to support for pre-existing theories and in accordance with this Order.

III. Conclusion

For the reasons stated above, the Court **GRANTS** Apotex's application for the limited amendments to add references to recently taken depositions, but which do not add new theories, new prior art, or discussion beyond that which Apotex has already stated in its Invalidity and Non-Infringement Contentions.

The Court **DENIES** leave to amend regarding Apotex's remaining proposed contentions as Apotex has failed to show good cause at this late stage of the litigation, especially given the likely prejudice to BMS and the disruption of the schedule.

IV. Recently Served Expert Reports

The parties were instructed by the Court to proceed with the expert disclosures pursuant to the schedule as it was set, with an indication that the Court would be available to discuss any alterations, should they be needed after a decision was rendered. On February 19, 2013, BMS filed a letter informing the Court that Apotex's expert reports contained arguments and references subject to the current application. *See* Docket Entry No. 117. Apotex responded, by letter dated February 20, that it believed it had complied with the Court's instructions to proceed with expert reports.

The Court has stated above which amendments will proceed and which are denied. The expert reports themselves are not before this Court, and the parties are responsible for reviewing the reports and ensuring they conform with this Order.

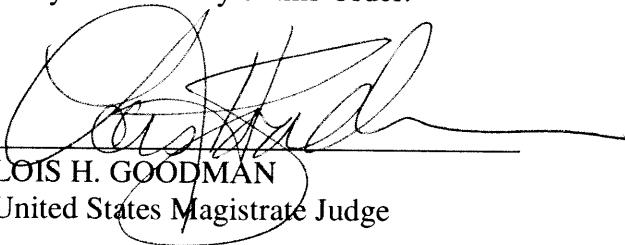
For the reasons stated above and for good cause shown,

IT IS on this **25th** day of **February, 2013**,

ORDERED that Apotex's application for leave to amend is **GRANTED in part** and **DENIED in part**; and it is further

ORDERED that Apotex shall submit its amended Non-Infringement and Invalidity Contentions within 10 days of the entry of this Order; and it is further

ORDERED that to the extent necessary, the parties shall serve amended reports in accordance with the rulings set forth above, within 10 days of the entry of this Order.



LOIS H. GOODMAN
United States Magistrate Judge

EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC

4 Plaintiff,

5 | vs.

6 ROXANE LABORATORIES, INC.,

7 Defendant.

. Case Nos. 11-cv-01241,
. 11-230

- Newark, New Jersey
- March 12, 2012

¹⁰ See also the discussion of the relationship between the concept of ‘cultural capital’ and the concept of ‘cultural value’ in the introduction.

⁸ See also the discussion of the relationship between the concept of ‘cultural capital’ and the concept of ‘cultural value’ in the introduction.

TRANSCRIPT OF RECORDED OPINION

Regarding defendant Roxane's request

for leave to amend invalidity contention

BY THE HONORABLE PATTY SHWARTZ

UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

6 For the Plaintiff: No one was present

For the Defendant: No one was present

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25 | Proceedings recorded by electronic sound recording; transcript produced by transcription service.

1 (Commencement of proceedings)

3 THE COURT: This matter has come before the Court
4 by way of defendant Roxane Laboratories Inc.'s request for
5 leave to amend its invalidity contentions regarding U.S.
6 Patent Number 6,248,770, hereinafter the "'770 Patent." For
7 the reasons set forth in this Opinion, the request for leave
8 to amend the invalidity contentions is denied.

9 By way of background, this case concerns a patent
10 for the methods of use and administration of alosetron
11 hydrochloride to treat Irritable Bowel Syndrome, hereinafter
12 "IBS." See the Complaint at paragraphs 9 and 10, filed
13 January 14, 2011, in Civil No. 11-230, ECF Number 1; and the
14 Amended Complaint at paragraphs 22 to 25 filed November 18,
15 2011; as well as the Complaint filed in Civil No. 11-1241.
16 IBS is a gastrointestinal diagnosis for patients with
17 abdominal pain, discomfort, and altered bowel function. See
18 the Plaintiff's Markman Brief at 2 filed December 9, 2011,
19 ECF Number 44 in Civil No. 11-230; and ECF Number 74 filed in
20 Civil No. 11-241. There are different classifications for
21 IBS, including: (1) diarrhea predominant; (2) constipation
22 predominant; and (3) IBS with alternating stool pattern. Id.

23 On September 4, 2001, the United States Patent and
24 Trademark Office issued the '770 Patent entitled "Medicaments
25 For the Treatment of Non-Constipated Female Irritable Bowel

1 Syndrome." ECF Number 1 filed in Civil No. 11-230; and ECF
2 Number 67 filed in Civil No. 11-1241. The U.S. Patent and
3 Trademark Office examined the '770 Patent, and on October 19,
4 2010, it issued reexamination certificate canceling or
5 amending the original claims. Id. The reexamined claims of
6 the '770 Patent cover methods of use and administration of
7 alosetron or a pharmaceutically acceptable derivative
8 thereof. Id.

9 Following reexamination, the '770 Patent was listed
10 in the Food and Drug Administration's, hereinafter "FDA,"
11 publication entitled "Approved Drug Products With Therapeutic
12 Equivalents Evaluations," which is also known as the "Orange
13 Book." See the Complaint at paragraph 11, filed Civil
14 No. 11-230, ECF Number 1; the Amended Complaint at
15 paragraph 26 filed in Civil No. 11-1241, ECF Number 67.

16 Plaintiff holds an approved new drug application
17 for alosetron hydrochloride tablets, which it sells under the
18 name LOTRONEX. See the Complaint filed January 14, 2011, at
19 paragraph 10 in Civil Action 11-230; the Amended Complaint
20 filed therein at paragraph 25; as well as ECF Number 67 at
21 Civil No. 11-1241.

22 Defendants filed an abbreviated new drug
23 application, hereinafter "ANDA," with the FDA to manufacture
24 and sell alosetron hydrochloride tablets before the '770
25 Patent expires, and submitted a "Paragraph IV certification"

1 | alleging that the original claims of the '770 Patent are
2 | invalid, unenforceable, and will not be infringed by the
3 | activities described in the defendant's ANDA. See the
4 | Original Complaint filed in 11-230, ECF Number 1 at
5 | paragraphs 12 through 14; the Amended Complaint at paragraphs
6 | 25 to 29, ECF Number 67 in Civil No. 11-1241.

7 | On January 14, 2011, plaintiff filed a complaint
8 | seeking a declaratory judgment that defendant's Paragraph IV
9 | certification and notice letter are defective because they do
10 | not address the reexamined claims of the '770 Patent. See
11 | ECF Number 1, Civil No. 11-230, the Complaint at paragraphs
12 | 18 through 24. The complaint alleges in the alternative that
13 | the defendant's submission of its ANDA before the expiration
14 | of the '770 Patent constitutes infringement. Id. at 26.

15 | On February 14, 2011, defendant filed an answer to
16 | the plaintiff's complaint. ECF Number 9.

17 | On March 4, 2011, the plaintiff filed a separate
18 | complaint against defendant for infringement of the '770
19 | Patent. See Civil No. 11-1241, ECF Number 1.

20 | On March 30, 2011, defendant filed an answer to
21 | that complaint. Id. at ECF Number 7.

22 | On July 28, 2011, the Court ordered that the two
23 | cases, Civil Nos. 11-230 and 11-1241 be consolidated for
24 | pretrial purposes only. See the Order dated July 28, 2011,
25 | Civil No. 11-1241, ECF Number 29.

1 On July 8, 2011, defendant served its invalidity
2 contentions. See the Joint Letter dated February 15, 2012,
3 Civil No. 11-230, ECF Number 49.

4 On December 9, 2011, both parties filed Markman
5 opening briefs. Civil No. 11-230, ECF Number 44; Civil
6 No. 11-1241, ECF Number 74. See also Civil No. 11-230, ECF
7 Number 45; and Civil No. 11-1241, ECF Number 75.

8 On February 10, 2012, the parties filed responsive
9 Markman briefs. See Civil No. 11-230, ECF Number 47; Civil
10 No. 11-1241, ECF Number 100; and Civil No. 11-1241, ECF
11 Number 101.

12 Defendant presented the instant request to amend
13 its invalidity contentions in a joint letter dated
14 February 15, 2012. Civil No. 11-230, ECF Number 49.

15 Defendant seeks to add two new invalidity contentions.

16 First, defendant seeks to add a contention that the '770
17 Patent is invalid for lack of written description under 35
18 U.S.C. § 112. Second, defendant seeks to add a contention
19 that the reexamined claims of the '770 Patent are invalid
20 under 35 U.S.C. § 305 for improper reexamination.

21 As to its first proposed invalidity contention,
22 defendant argues that plaintiff's proposed construction of
23 the claim term "experienced symptoms for at least six
24 months," fails to disclose a step of assessing whether an IBS
25 patient has experienced IBS symptoms with diarrhea being

1 predominant for at least six months. Defendant argues that
2 good cause exists to now add a claim of invalidity based upon
3 on alleged lack of written description because plaintiff's
4 proposed claim construction was unavailable to defendant when
5 it served its invalidity contentions in July 2011.

6 As to its second proposed invalidity contention,
7 defendant argues that plaintiff's litigation contention that
8 a reference entitled "New Product Makes a Difference,"
9 published by Glaxo Wellcome in Magnet July 19, 1997, and a
10 publication in Rubicon entitled "For Women Only," published
11 in 1997 are being viewed in litigation as not prior art, and
12 that this position is inconsistent with the plaintiff's
13 position before the U.S. Patent and Trademark Office to whom
14 it represented that those references were, in fact, prior
15 art. The defendant asserts that if these references, namely
16 the Magnet and Rubicon references, are not prior art,
17 reexaminations based upon this prior art before the Patent
18 and Trademark Office was improperly initiated. Defendant
19 argues that good cause exists because it had no way to
20 anticipate that plaintiff would contend in this case that the
21 Magnet and Rubicon references are not prior art because
22 plaintiff used this prior art as a basis for initiating
23 reexamination proceedings.

24 Defendant also contends that its request to add
25 this contention is not untimely because defendant has been

1 working on obtaining foreign discovery from a third party,
2 namely GlaxoSmithKline, for several months regarding the
3 prior art issue, and notified plaintiff that it sought to
4 amend its invalidity contentions once it became apparent that
5 defendant would not obtain that foreign discovery until late
6 in the discovery period.

7 Defendant also argues that amending its invalidity
8 contentions will not delay the resolution of this case or
9 prejudice plaintiff because this request comes months before
10 the close of fact discovery, no depositions have been taken,
11 and no third-party documents have been produced. In
12 addition, with respect to its invalidity contention based
13 upon lack of written description, defendant asserts that such
14 an amendment presents no new issues beyond those addressed in
15 the parties' Markman briefing, and plaintiff is in the best
16 position to know the facts relevant to the requested
17 amendment.

18 Plaintiff argues that amendments to invalidity
19 contentions are not liberally granted, defendant does not
20 have good cause to amend, and defendant's request is not
21 timely. As to the defendants' first proposed contention,
22 plaintiff argues that: (1) there's no good cause to permit an
23 amendment because plaintiff identified its construction of
24 the term "experienced symptoms for at least six months," more
25 than four months ago, and defendant offers no explanation for

1 its failure to seek amendment during that time period; and
2 (2) defendant has been on notice for more than one year that
3 plaintiff's claim construction was directed towards the
4 treatment of IBS where diarrhea is predominant.

5 As to defendant's second proposed contention,
6 plaintiff argues that: (1) there is no good cause to amend
7 because defendant delayed seeking amendment of its contention
8 to add a defense under § 305 for more than five months; (2)
9 defendant's justification for its delay due to foreign
10 discovery is baseless; and (3) the proposed contention is
11 directed to an affirmative defense that is not pled in
12 defendant's answer.

13 Plaintiff also asserts that it relied on
14 defendant's existing invalidity contentions to develop its
15 case strategy, and thus the amendments would result in
16 prejudice.

17 L. Pat. R. 3.7 of the local rules of the United
18 States District Court for the District of New Jersey, which
19 governs amendments to invalidity contentions, provides:
20 "Amendment of the infringement contentions or the invalidity
21 contentions may be made by order of the court upon a timely
22 application and showing of good cause. The application shall
23 disclose whether the adverse party consents or objects.
24 Non-exhaustive examples of circumstances that may, absent
25 undue prejudice to the adverse party, support a finding of

1 good cause, include: (a) a claim construction by the court
2 different from that proposed by the party seeking amendment;
3 (b) recent discovery of material prior art, despite earlier
4 diligent search; (c) recent discovery of non-public
5 information about the accused instrumentality which was not
6 discovered, despite diligent efforts, before the service of
7 the infringement contentions; and (d) disclosure of an
8 asserted claim and infringement contention by a Hatch-Waxman
9 Act plaintiff under L. Pat. R. 33.6(f), that requires
10 response by defendant because it was not previously presented
11 or reasonably anticipated. The duty to supplement discovery
12 responses under Fed. R. Civ. P. 26(e) does not excuse the
13 need to obtain leave of court to amend contentions."

14 L. Pat. R. 3.7. Thus, pursuant to Rule 3.7, the Court may
15 permit a party to amend its invalidity contentions provided
16 the following three elements are established: (1) the moving
17 party makes a timely application to the court; (2) there is
18 good cause for the amendment; and (3) there is no undue
19 prejudice to the adverse party.

20 Federal Circuit precedent governs the
21 interpretation of local patent rules because such issues are
22 "intimately involved in the substance of enforcement of the
23 patent right." O2 Micro International Ltd. v. Monolithic
24 Power Systems Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006)
25 (internal quotation marks and citations omitted). The patent

1 rules governing contentions are designed to encourage parties
2 to provide "early notice of their infringement and invalidity
3 contentions and to proceed with diligence in amending those
4 contentions when new information comes to light in the course
5 of discovery." O2 Micro, 467 F.3d at 1365 to 66. The local
6 rules "seek to balance the right to develop new information
7 in discovery with the need for certainty as to the legal
8 theories." O2 Micro, 467 F.3d at 1366. The local rules
9 require "parties to crystallize their theories of the case
10 early in the litigation." Id. at 1364 (internal quotations
11 and citations omitted).

12 Amendments to infringement and invalidity
13 contentions are not granted as liberally as requests for
14 amendments to pleadings, in part, because "the philosophy
15 behind amending claim charts is decidedly conservative and
16 designed to prevent the 'shifting sands' approach," to a
17 party's contentions. King Pharmaceuticals Inc. v. Sandoz
18 Inc., Civil No. 08-5974, 2010 WL 20015258 at *4 (D.N.J.
19 May 20, 2010) (internal quotation marks and citations
20 omitted). Cf. Fed. R. Civ. P. 15(a)(2).

21 New Jersey's local patent rules require that the
22 party seeking leave to amend demonstrate that it has made a
23 "timely application." L. Pat. R. 3.7. The Federal Circuit
24 has emphasized the importance of this element recognizing
25 that "if the parties were not required to amend their

1 | contentions promptly after discovering new information, the
2 | contention requirement would be virtually meaningless as a
3 | mechanism for shaping the conduct of discovery in trial
4 | preparation." O2 Micro, 467 F.3d at 1366.

5 | Defendant has not timely moved to amend its
6 | invalidity contentions to include the contention that
7 | plaintiff's proposed construction for the claim term
8 | "experienced symptoms for at least six months" fails to
9 | satisfy the written description requirement under 35 U.S.C.
10 | § 112. Section 112 requires "a written description of the
11 | invention and of the manner and process of making and using
12 | it ... as to enable any person skilled in the art to which it
13 | pertains ... to make and use the same ..." 35 U.S.C. § 112.
14 | Defendant claims that plaintiff's proposed claim construction
15 | shows that the patent fails to disclose the step of assessing
16 | whether an IBS patient has experienced IBS with diarrhea
17 | being predominant symptoms for at least six months and
18 | therefore would not allow a "person skilled in the art" to
19 | determine to undertake that additional step of assessment.

20 | To know if a patent is invalid for "lack of written
21 | description," a party must show that "the disclosure of the
22 | application relied upon reasonably conveys to those skilled
23 | in the art that the inventor had possession of the claimed
24 | subject matter as of the filing date." Bard Peripheral
25 | Vascular Inc. v. W.L. Gore & Associates Inc., Civil

1 No. 10-1510, 2012 WL 4014373 at *14 (D.N.J. February 10,
2 2012) (quoting Ariad Pharmaceuticals Inc. v. Eli
3 Lilly & Company, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). This
4 requires consideration of the patent itself and any
5 reexamination certificates. The defendant has had access to
6 these documents since the inception of the case, as both of
7 these documents were included in the plaintiff's original
8 complaints. Defendant acknowledges that plaintiff introduced
9 the term "experienced symptoms for at least six months"
10 during reexamination, see the proposed invalidity contention
11 at 65, and the record shows that the U.S. Patent and
12 Trademark Office reissued a reexamination certificate for the
13 '770 Patent on October 19, 2010, approximately 16 months ago.
14 See the Complaint, ECF Number 1 at paragraphs 17 to 19, as
15 well as filed in Civil No. 11-1241 and Civil No. 11-230, ECF
16 Number 1. Thus, the documents that form the basis for the
17 lack of written description invalidity contention have
18 existed since at least October 2010. At a minimum, defendant
19 was in possession of these documents at least since the time
20 it was served with the complaint on January 14, 2011. Thus,
21 defendant's proposed contention that persons skilled in the
22 art would not be able to determine that they had to undertake
23 the alleged additional step, could have been raised in
24 defendant's original contentions.

25 Moreover, even if this contention existed only

1 under plaintiff's proposed construction of the claim term,
2 that construction was disclosed on September 23, 2011, and
3 defendant waited five months to seek to amend its invalidity
4 contentions to address it. Filing a request to amend five
5 months after having the facts upon which to seek to amend it,
6 constitutes an untimely application. See O2 Micro, 467 F.3d
7 at 1367, where it denied leave to amend where the moving
8 party waited almost three months to file its motion. Cf.
9 Mintz v. Dietz and Watson, Civil No. 05-1470, 2009 WL 1868711
10 at *2 (S.D. Cal. June 29, 2009), where the court granted the
11 motion where it was filed three days after the discovery of
12 the new information; and Streak Products Inc. v. Antec Inc.,
13 Civil No. 09-04255, 2010 WL 351752 at *1-2 (N.D. Cal.
14 September 8, 2010), where the court granted leave to a party
15 who filed its application within 10 days of discovering the
16 new information.

17 This application comes five months after the
18 discovery of the fact that the defendant now contends, gives
19 rise to the need to amend. This is an untimely request, and
20 therefore it is being denied.

21 Defendant also seeks to amend its contention to
22 include the contention that the '770 Patent was improperly
23 reexamined under 35 U.S.C. § 305. Section 305 allows a
24 patent owner to "propose any amendment to its patent and a
25 new claim or claims thereto in order to distinguish the

1 invention as claimed from the prior art cited under the
2 provisions of § 301 [of title 35] or in response to a
3 decision adverse to the patentability of a claim of a
4 patent." 35 U.S.C. § 305. Defendant claims that plaintiff's
5 reexamination was improper as reflected by its present
6 position concerning certain references it presented during
7 the reexamination; specifically, plaintiff now contends that
8 the Magnet and Rubicon references are not prior art, but it
9 told the U.S. Patent and Trademark Office that these
10 references were prior art. Defendant asserts that if the
11 Magnet and Rubicon references are not prior art, as plaintiff
12 now contends, then the reexamined claims are invalid under
13 § 305 because they were not added or amended during
14 reexamination to distinguish prior art.

15 To show improper reexamination under 35 U.S.C.
16 § 305, defendant must prove that plaintiff added new claims
17 that enlarged the scope of the patent's coverage. See Cordis
18 Corp. v. Medtronic AVE Inc., 511 F.3d 1157, 1185 (Fed. Cir.
19 2008). Under § 305, the Federal Circuit requires courts to
20 consider only whether the added claim broadened the scope of
21 coverage of the original patent. Id. "In determining
22 whether a patentee broadened a reexamined claim under 35
23 U.S.C. § 305, this court uses the same test as for reissue
24 claims ... [a] claim is enlarged if it includes within its
25 scope any subject matter that would not have infringed the

1 original patent." Hockerson-Halberstadt Inc. v. Converse,
2 183 F.3d 1369, 1374 (Fed. Cir. 1999) (internal quotation
3 marks and citations omitted). The focus under § 305,
4 therefore, is on the plaintiff's actions before the U.S. PTO
5 and not whether a particular item is or is not, in fact,
6 prior art, and the defendant has cited no law to the
7 contrary. Because defendant has had access to the
8 reexamination materials since at least the time it was served
9 in this case and it had an opportunity to assert that the
10 patent was invalid based upon plaintiff's actions during the
11 reexamination when it served its original contentions,
12 plaintiff's subsequent litigation position did not impact
13 defendant's ability to have done so.

14 Moreover, even if plaintiff's litigation position
15 as to the prior art status of Magnet and Rubicon were
16 relevant to the propriety of the reexamination, plaintiff
17 took that position concerning whether or not Magnet and
18 Rubicon were prior art on August the 22d, 2011, in response
19 to defendant's original invalidity contentions. Defendant's
20 six-month delay in seeking relief constitutes an untimely
21 application. See O2 Micro, 467 F.3d at 1367. Thus,
22 defendant's request to amend its proposed invalidity
23 contention under 35 U.S.C. § 305 is denied as untimely.

24 The Court also considers whether good cause exists.
25 New Jersey's local patent rules also require the party

1 seeking leave to amend to demonstrate that it has made a
2 "showing of good cause." L. Pat. R. 3.7. Good cause
3 "requires a showing of diligence." O2 Micro, 467 F.3d at
4 1366. And the "burden is on the movant to establish
5 diligence, rather than on the opposing party to establish a
6 lack of diligence." Id. (internal citations omitted). The
7 good cause showing "requires diligence throughout the
8 discovery process and that the moving party not only must act
9 promptly upon discovery of new [information], but also must
10 establish that it was diligent in its search." West v.
11 Jewelry Innovations Inc., Civil No. 07-1812, 2008 WL 4532558
12 at *2 (N.D. Cal. October 8, 2008); Streak Products, 2010 WL
13 3515752 at *2. As such, the Court "must address whether the
14 party was diligent in discovering the basis for the proposed
15 amendment." West, 2008 WL 4532558 at *2.

16 The local rules give four non-exhaustive examples
17 of good cause, two of which focus on the moving party's
18 diligence in locating the newly discovered information and
19 its explanation for not including it in the original
20 contention. L. Pat. R. 3.7. See O2 Micro, 467 F.3d at 1367.
21 See also King Pharmaceuticals, 2010 WL 2015258 at 4.
22 According to Rule 3.7, examples of situations for good cause
23 may be found, include: "(a) a claim construction by the court
24 different from that proposed by the party seeking amendment;
25 (b) recent discovery of material prior art despite early

1 diligent search; [and] (c) recent discovery of non-public
2 information about the accused instrumentality which was not
3 discovered despite diligent efforts before the service of the
4 infringement contentions ..." L. Pat. R. 3.7.

5 This, of course, is not a situation where an
6 amendment is necessitated by unexpected court action, nor
7 does it involve the recent discovery of material prior art or
8 the recent discovery of non-public information. Defendant
9 claims that the proposed construction of the claim term
10 "experienced symptoms for at least six months" forms its
11 basis for seeking to amend its invalidity contention under
12 § 112.

13 As stated previously, defendant was or should have
14 been aware of the necessary information underlying its
15 contention concerning an alleged lack of written description
16 since the inception of the case, because such a contention is
17 based upon the patent and the reexamination certificate. If
18 defendant failed to formulate this invalidity contention,
19 despite having the necessary information to do so, it cannot
20 show it acted with diligence to constitute good cause. Even
21 if plaintiff's claim construction was relevant to the
22 defendant's lack of written description contention, defendant
23 has had access to that construction since September 23, 2011.
24 Thus, defendant has been on notice of any potential basis of
25 invalidity arising from plaintiff's claim construction for at

1 least four and a half months. Defendant does not offer any
2 excuse for its failure to formulate the lack of written
3 description contention during that period and hence has not
4 shown cause for its failure to act on this information.

5 Moreover, as stated previously, defendant also
6 claims that plaintiff's contention that the Magnet and
7 Rubicon references are not prior art in contrast to its
8 position before the U.S. PTO forms the basis for its proposed
9 invalidity contention under § 305. As discussed previously,
10 defendant had sufficient information to assess the propriety
11 of the reexamination since the inception of the case. If
12 plaintiff failed to formulate this invalidity contention,
13 despite having the necessary information to do so, it cannot
14 show the diligence required to constitute good cause under
15 the local rules. Moreover, even if plaintiff's litigation
16 position as to the prior art status of Magnet and Rubicon
17 were relevant, see the defendant's "improper reexamination"
18 contention, defendant has known about plaintiff's position
19 since August 22, 2011. Thus, defendant was on notice for at
20 least five and a half months of any potential basis of
21 invalidity arising therefrom. Defendant does not offer any
22 excuse for its failure to formulate the improper
23 reexamination contention during that period and hence has not
24 satisfied the good cause requirement under L. Pat. R. 3.7.

25 Finally, defendant's effort to excuse its delay

1 based upon the status of discovery from non-party
2 GlaxoSmithKline is unavailing. First, there is no indication
3 that any discovery from any non-party has any bearing on the
4 proposed contentions. If it did, defendant would have been
5 unavailable to make this application because it would have
6 lacked sufficient information to do so. To the contrary,
7 defendant has had all the information it need to formulate
8 these contentions and make this application for months.

9 Second, even if GlaxoSmithKline had information
10 relevant to defendant's invalidity contentions, the parties
11 have been aware that GlaxoSmithKline may have relevant
12 information since before the June 3, 2011, Rule 16 conference
13 and could have taken steps at any time to secure documents
14 from that entity.

15 For these reasons, the defendant has not provided
16 good cause for amending its contentions to add assertions
17 that plaintiff's patent is invalid for lack of written
18 description or improper reexamination.

19 Now, of course, the Court only needs to consider
20 undue prejudice if the moving party moved timely and made the
21 requisite showing of good cause. O2 Micro, 467 F.3d at 1368.
22 But because the defendant has not shown that it acted with
23 diligence or made a timely application, the Court need not
24 consider whether the amendment would unduly prejudice the
25 plaintiff.

For all of these reasons, the defendant's request
for leave to amend its invalidity contentions is denied.

A form of Order consistent with this Opinion will be issued.

5 (Conclusion of proceedings)

1 | Certification

I, SARA L. KERN, Transcriptionist, do hereby certify
that the 21 pages contained herein constitute a full, true,
and accurate transcript from the official electronic
recording of the proceedings had in the above-entitled
matter; that research was performed on the spelling of proper
names and utilizing the information provided, but that in
many cases the spellings were educated guesses; that the
transcript was prepared by me or under my direction and was
done to the best of my skill and ability.

11 I further certify that I am in no way related to any of
12 the parties hereto nor am I in any way interested in the
13 outcome hereof.

14

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S/ *Sara L. Kern*

March 13, 2012

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* ALSO ADMITTED IN NEW YORK

+ ALSO ADMITTED IN PENNSYLVANIA

- ONLY ADMITTED IN NEW YORK

PLEASE REPLY TO ROSELAND, NJ

May 14, 2012

VIA ECF AND FEDERAL EXPRESS

Hon. Mark Falk, U.S.M.J.
United States Post Office & Courthouse
1 Federal Square, Room 457
Newark, New Jersey, 07101-0999

Re: Noven Pharmaceuticals v. Watson Laboratories, Inc. et al.,
Civ. No. 11-5997 (DMC/MF)

Dear Judge Falk:

Pursuant to L. Pat. R. 3.7, Watson respectfully seeks leave to amend its invalidity contentions to: (1) identify additional claims that are invalid under 35 U.S.C. § 112, ¶ 1, for lack of written description; (2) add additional supporting evidence from the file histories of related patent applications owned by Plaintiff in support of Watson's previously asserted defenses under 35 U.S.C. §§ 102 and 103; and (3) add three prior art references cited in those file histories. (Ex. A, Am. Contentions Redline, pp. 50-67, 97, 125, 128-33.)

Watson discovered the additional claim defects and this additional supporting evidence while preparing Watson's claim construction positions for the parties' April 27, 2012 exchange of preliminary claim constructions and supporting evidence pursuant to this Court's January 20, 2012 Scheduling Order. (Dkt. 29, Scheduling Order, ¶ 6.)

Watson promptly notified Plaintiff of its decision to seek leave on April 26 – the very same day that Watson realized the need for an amendment and on May 2 provided Plaintiff with a

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redlined draft of Watson's proposed contentions.¹ (Ex. B, 4/27-5/2 Emails Lydigsen & Dahiya.) In response to Plaintiff's May 4 request, on May 7, Watson summarized its good cause for amending. (*Id.*, 5/4-5/7 Emails Lydigsen & Pe.) On May 9, Plaintiff refused consent, claiming that Watson's amendment – even at this early pre-claim construction stage is “inexcusable.” (*Id.*, 5/9 Email Pe to Lydigsen.)

Good cause for amendment exists given Watson's recent discovery of the subject matter it seeks to add to the contentions, the early pre-claim construction stage of the litigation and the fact that Noven will suffer no prejudice as a result of the amendment.

I. **Background of Watson's Invalidity Contentions**

As Your Honor may recall, and by way of background, this action for alleged patent infringement arises out of the filing of Watson Laboratories, Inc.'s Abbreviated New Drug Application (“ANDA”) No. 200147, which seeks approval to market and sell generic methylphenidate transdermal patches of certain dosages. Plaintiff, which markets and sells the branded product, Daytrana®, filed suit on October 13, 2011, claiming that Watson's proposed generic products infringe U.S. Patent Nos. 6,210,705 (“‘705 patent”) and 6,348,211 (“‘211 patent”) (collectively, “patents-in-suit”). Watson denies the allegations and seeks a declaration that the patents-in-suit are invalid and/or are not infringed.

Based on Watson's claims that the patents-in-suit are invalid, and pursuant to this Court's January 20, 2012 Scheduling Order (Dkt. 29), Watson served its invalidity contentions in accordance with L. Pat. R. 3.3 and 3.6 two weeks later on February 3, 2012. Watson's contentions included a 110-page narrative detailing Watson's invalidity positions as well as a 58-page claim chart pin-pointing the prior art's disclosure of each limitation of the asserted claims for which Watson alleges anticipation and/or obviousness. On the same day, Watson also submitted its 26-page non-infringement contentions. Although Watson's invalidity contentions alleged anticipation and obviousness of the asserted claims, Watson inadvertently omitted citations to two anticipatory references as to several specific limitations in the original chart.

¹ In an effort to make this amendment as comprehensive as possible, Exhibit A contains several additional clarifying revisions to the redlined draft provided to Plaintiff on May 2. First, Defendants have added a statement reserving their right to rely on the file histories of all related and foreign counterpart applications of the patents-in-suit. (Ex. A, Am. Contentions, pp. 51, 125.) Second, Defendants have corrected two unintentional omissions from the Claim Chart Redline. Specifically, Defendants have added a citation to the '286 patent for the “rate in excess of 0.05 mg/kg/hr” limitation of claim 31 of the ‘211 patent (*Id.*, Am. Chart, pp. 94) and have added several pin cites to each new citation to U.S. Patent No. 5,656,286 (“‘286 patent”) (e.g., *id.*, pp. 6-7 (adding pin cites to col. 1, ll. 46-54, col. 4, ll. 20-23, col. 10, ll. 12-19, col. 28, l. 7, col. 32, ll. 51-65, col. 34, ll. 60-62, col. 35, ll. 4-8)).

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Following a dispute between the parties as to whether Watson's contentions and accompanying claim chart were sufficiently clear, Watson served a replacement chart on February 20. Plaintiff objected to the replacement chart as improperly seeking an amendment to the invalidity contentions without leave of Court. Watson then sought an order from the Court permitting the replacement of the original chart with the corrected chart. On March 6, this Court issued an order permitting Watson to replace the chart. The Court noted that Watson "promptly sought to clarify/amend their contentions and charts" and that there would be "no undue prejudice or delay that will result from allowing the replacement contentions and/or claim charts at this early stage of the proceedings." (*Id.*, ¶ 5).

II. Good Cause Exists For Watson's Prompt Request For Leave To Amend

Watson has good cause to amend its invalidity contentions in light of the new defenses and evidence it discovered in the course of investigating claim construction positions. This Court considers four factors in determining whether good cause exists under L. Pat. R. 3.7: (1) the reason for the delay and whether a party has been diligent; (2) the availability of a continuance and potential impact of a delay on judicial proceedings; (3) the danger of unfair prejudice; and (4) the importance of what is being excluded. *Oy Ajat, Ltd. v. Vatech Am., Inc.*, No. 10-4875 (PGS), 2012 WL 1067900, at *20 (D.N.J. Mar. 29, 2012).

As detailed below, good cause exists for Watson to amend its invalidity contentions at this early stage to incorporate defenses and new evidence discovered as a result of Watson's timely development and investigation of its claim construction positions. (Dkt. 29, Scheduling Order, ¶ 6); *see Arbitron, Inc. v. Int'l Demographics Inc.*, No. 2:06-CV-434 (TJW), 2008 WL 4755761, at *2 (E.D. Tex. Oct. 29, 2008). These additions to Watson's potentially dispositive invalidity defenses at this early stage will neither delay the proceedings nor prejudice Plaintiff.

A. Watson's Timely Claim Construction Investigation Led to the Discovery of Section 112 Invalidity Defenses and New Supporting Evidence

On April 26, Watson was finalizing its preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a) and (b) and this Court's January 20, 2012 Scheduling Order. In an effort to identify evidence potentially relevant to claim construction, Watson initiated a review of the file histories of several European counterpart applications as well as the file histories of several U.S. patent applications related to the patents-in-suit.² Watson's review of these file histories alerted Watson to: (1) the fact that additional limitations of the patents-in-suit are invalid pursuant to 35 U.S.C. § 112, ¶ 1 for failure to meet the written description requirement; (2) the United States Patent and Trademark Office's ("USPTO") rejection of many of the arguments on

² Attached as Exhibit C is a family tree showing the relationship between the patents-in-suit, the European counterpart applications, and the subsequently filed U.S. patent applications, which claim priority to the patents-in-suit. Notably, application nos. 12/981,154 and 13/071,048 are still pending. The file histories of these applications are Noven's documents.

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which Plaintiff relies to refute Watson's invalidity defenses pursuant 35 U.S.C. §§ 102 and 103; and (3) three pieces of additional prior art cited during the prosecution of subsequently-filed applications related to the patents-in-suit.

Watson's review of the European counterpart file histories on April 26 revealed that claims nearly identical in scope to the asserted claims of the '705 patent were rejected based on inadequate specification support. Specifically, both the original claims of European Application No. 98963179.0 and every asserted claim of the '705 patent require that the "composition comprises no more than about 5 wt % of acid functional monomers."³ (hereinafter, "wt % limitation"). However, neither the European specification nor the '705 specification describe a composition in which the total combined amount of acid functional monomers in the component parts is no more than about 5 % by weight. Watson determined that the European Patent Office's ("EPO") rationale for rejecting the claims of the European counterpart demonstrated that the asserted claims of the '705 patent are invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1.

Immediately upon discovering this fatal defect on April 26, Watson contacted Plaintiff's counsel to apprise Plaintiff of this additional section 112 defense and Watson's intent to seek leave to amend its invalidity contentions (Ex. B, 4/27-4/28 Emails Dahiya & Lydigsen), even though Watson's review of the materials was ongoing. Plaintiff's counsel requested a redlined copy of the proposed amended contentions before making a decision on whether Plaintiff would consent to Watson's proposed amendment. (*Id.*) Watson responded, advising that its review was ongoing, and that it would provide Plaintiff with a redlined draft of Watson's proposed amendment once Watson had completed its review of the relevant materials. (*Id.*) In the interim, Watson laid out its written description defense for the wt % limitation, including citations to the European counterpart's file history, in its preliminary proposed claim construction submission on April 27. (Ex. D, Watson Claim Constr., pp. 4-7)

Watson's review of the European counterpart file histories continued in the late evening of April 26 and into April 27. The EPO's rejection of claims of European Patent Application No. 04004843.1 that contained broad rate and duration limitations lacking any basis in the application, prompted Watson to consider whether the similarly broad limitations of claims 22-26 and 30-31 of the '211 patent are likewise invalid under 35 U.S.C. § 112, ¶ 1 due to inadequate written description support.

³ Independent claims 16, 18, and 25 include the same requirement, but are worded slightly differently to require that "acid functional monomers are present in an amount of no more than about 5 wt %." Dependent claims 17 and 24 contain a limitation requiring that the "acid functional monomers are present in an amount of no more than about 1 wt %," which suffers from the same written description deficiency as the 5 wt % limitation.

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Watson's review then turned to the file histories of the related U.S. applications.⁴ This review revealed additional evidence in support of Watson's previously asserted invalidity defenses under 35 U.S.C. §§ 102 and 103, including a decision by the USPTO Board of Appeals and Interferences upholding the rejection of Plaintiff's patent claims as obvious.⁵ These file histories also alerted Watson to the significance of three new prior art references (U.S. Patent Nos. 5,446,070 and 5,574,090 and JP H2-255611) and additional disclosures – as understood by a person of ordinary skill – of one reference on which Watson relied in its original contentions (the '286 patent).⁶

On May 2, 2012, Watson provided Plaintiff with a redlined version of its proposed amendment, which included the section 112 defect previously identified by Watson on April 26, the additional section 112 defects and the supplemental supporting evidence for Watson's existing anticipation and obviousness defenses, which were uncovered by Watson's review over the next several days. (Ex. B, 5/2 Email Lydigsen to Dahiya.) On May 4, Plaintiff requested that Watson explain the good cause for the proposed amendment, and Watson responded to Plaintiff's request on May 7, summarizing its good cause. (*Id.*, 5/4-5/7 Emails Lydigsen & Pe.) On May 9, Plaintiff refused consent, calling Watson's amendment "wholly improper" and "inexcusable." (*Id.*, 5/9 Email Pe to Lydigsen.)

B. Watson's Early Pre-Claim Construction Amendment Will Neither Delay the Proceedings Nor Prejudice Plaintiff

Good cause exists here because Watson's amendments at this early stage in the litigation will not delay the proceedings or prejudice Plaintiff.

Watson's amended invalidity contentions will have no effect on this Court's schedule, given that little more than document production has occurred in this case. Claim construction is just beginning; opening claim construction briefs are not due until July 20, 2012. (Dkt. 29, Scheduling

⁴ Plaintiff's counsel's assertion that Watson was not diligent because it did not "learn[]" of the relevance of these file histories" prior to submitting its invalidity contentions (Ex. B, 5/9 Email Pe to Lydigsen) contrasts sharply with Plaintiff's prior objection to producing the file histories because they are allegedly "neither relevant to any claim or defense nor reasonably calculated to lead to the discovery of admissible evidence." (Ex. E, Sidley Objections, pp. 14-16.)

⁵ The bulk of Watson's amendment consists of a discussion of these file histories, which are Noven's documents and merely lend further support to Watson's February 3 contentions. (Ex. A, Contentions, pp. 50-67.) This amendment is also warranted at this time because the USPTO's rationale contradicts Plaintiff's positions on non-obviousness.

⁶ As evidenced by Watson's identification of over 70 material prior art references in its 110-page invalidity contentions and accompanying 58-page L. Pat. R. 3.3(c) chart, Watson engaged in extensive searching prior to submitting its February 3 contentions. Despite these diligent efforts, Watson did not uncover the prominent role these 4 prior art references played in the related U.S file histories and thus, in turn, their significance to the patents-in-suit.

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Order ¶ 10.) Further, no depositions have been taken, fact discovery will not close until November 2, 2012, opening expert reports are not due until November 30, 2012, and no trial date has been set. (*Id.*, ¶¶ 8, 17 & 20.) Thus, Watson's amended invalidity contentions will have no effect on this Court's schedule.

Plaintiff's claim of prejudice in its email refusing consent rings hollow given the early pre-claim construction stage of this litigation. (*See* Ex. B, 5/9 Email Pe to Lydigsen.) Noven's complaint that it has somehow been prejudiced because it has already "identified terms for claim construction, and proposed constructions and provided cited support," is belied by the facts. First, Watson notified Noven of its intent to amend *before* the deadline for exchanging claim constructions and offered to extend the deadline in light of the amendment. (*See id.*, 4/27 Emails Lydigsen & Dahiya.) Noven cannot claim prejudice given that it nonetheless chose to proceed with the exchange on schedule. Second, on May 4, Noven revised its proposed constructions for the wt % limitation in an apparent attempt to combat the section 112 defense Watson seeks to add to its contentions. (*See* Ex. F, 5/4 Email Pe to Lydigsen.) In support of its new constructions, Noven relies on the file histories of the same U.S. related applications that it seeks to prevent Watson from adding to its invalidity contentions. (*Id.*, 5/8 Email Pe to Lydigsen (citing file histories of U.S. Patent Application Nos. 10/024,513 and 11/812,198).) Moreover, Plaintiff's claim construction amendment underscores the fact that Plaintiff has sufficient time to adjust its strategy to account for Watson's amendment and will not be prejudiced here.

Indeed, courts have frequently granted leave to amend when the litigation is at similarly early stages due to the lack of prejudice to the plaintiff. *See Arbitron*, 2008 WL 4755761, at *1-2 (permitting additional indefiniteness defense despite 7-month delay where a claim construction hearing had not yet occurred "[g]iven the importance of the indefiniteness defense to [the defendant] and the absence of any potential prejudice to the plaintiff in allowing the amendment . . ."); *see also Streak Prods. Inc. v. Antec, Inc.*, No. C09-04255 RS (HRL), 2010 WL 3515752, at *2 (N.D. Cal. Sept. 8, 2010) (allowing amendment where there was "no discovery deadline or trial date yet set" allowing "plenty of time to analyze and conduct discovery" related to the amended invalidity contentions); *Avago Techs. Gen. IP PTE Ltd. v. Elan Microelecs. Corp.*, No. C04-05385 JW (HRL), 2007 WL 1449758, at *2 (N.D. Cal. May 15, 2007) (granting leave where plaintiff would "have known about th[e] theory for almost three months before its opposition to the relevant summary judgment motion is due" and "all of the documents that th[e] theory is based on have been in [plaintiff's] possession . . ."); *Computer Acceleration Corp. v. Microsoft Corp.*, 481 F. Supp.2d 620, 627 (E.D. Tex. 2007) (granting leave to amend invalidity contentions despite the defendant's "dilatory conduct" due to the "lack of unfair prejudice to [plaintiff]" and "ample opportunity for [plaintiff] to respond to the new invalidity contentions").

C. Public Policy Favors Amendment

Moreover, the public policy in favor of deciding issues of patent invalidity on their merits weighs in favor of granting leave here. *See Avago*, 2007 WL 1449758, at *2 ("[T]he court wishes to have this invalidity issue decided on its merits in the interest of promoting substance over form."); *Streak Prods.*, 2010 WL 3515752, at *3 ("Courts prefer to decide case[s] on the merits, rather than on procedural grounds."). Watson, and the public, should not be denied the opportunity

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to present the strongest case possible for invalidating the patents-in-suit merely because Watson did not learn of the evidence contained in the file histories of the related applications until after the submission of its invalidity contentions on February 3.

In sum, and as this Court noted in its prior order, L. Pat. R. 3.7 “is not a straightjacket into which litigations are locked from the moment their contentions are served [and] flexibility exists, at least near the outset.” (Dkt. 36, Order (citing *THF Publ’n, Inc. v. Doskocil Mfg. Co.*, 705 F. Supp.2d 361, 365-66 (D.N.J. 2010)).) Leave to amend is warranted here where Watson only recently discovered the section 112 defenses and supporting evidence for its existing defenses, the amendment will not delay the case, and the amendment will not prejudice Plaintiff.

Accordingly, Watson respectfully requests that this Court grant Watson leave to amend its invalidity contentions pursuant to L. Pat. R. 3.7

Respectfully,

s/ Liza M. Walsh

Liza M. Walsh

LMW/pxm

Cc: All Counsel of Record via ECF and Email

EXHIBIT 5

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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ABRAXIS BIOSCIENCE, LLC and
CELGENE CORPORATION,

Plaintiffs,

v.

ACTAVIS LLC,
Defendant.

Civ. A. No. 2:16-cv-01925 (JMV-MF)

**DEFENDANT'S PROPOSED CLAIM
TERMS FOR CONSTRUCTION**

Pursuant to Local Patent Rule 4.1 for the United States District Court for the District of New Jersey, and this Court's August 17, 2016 Scheduling Order (DE No. 46), Defendant/Counterclaim Plaintiff Actavis LLC ("Actavis"), based on evidence available to it now, provides the following list of claim terms which Defendant contends should be construed by the Court to Plaintiffs/Counterclaim Defendants Abraxis Bioscience, LLC and Celgene Corporation (collectively "Plaintiffs").

Defendant expressly reserves the right to make any modifications, additions or deletions to the list of claim terms identified below after receiving Plaintiffs' list of claim terms which Plaintiffs contend require construction or as a result of further discussions with Plaintiffs. Additionally, because claim construction discovery is ongoing, Defendant expressly reserves the right to update, supplement, revise, or otherwise modify this list of proposed claim terms requiring construction, in light of further investigation and discovery, including evidence not yet received. This list of proposed terms shall not be construed as: (i) an admission that any particular claim language requires construction beyond its plain and ordinary meaning as understood by a person of ordinary skill in the art; or (ii) an admission that any particular claim language constitutes a substantive claim limitation.

Subject to the foregoing, Defendant identifies the following claim terms as requiring construction by the Court:

U.S. Patent No(s).	Claim #	Term
7,820,788; 7,923,536; 8,138,229	'788 patent: 1-9 '536 patent: 1-4, 7, 8, 11, 14 '229 patent: 1-3, 6-8, 11-	"weight ratio of albumin to paclitaxel in the composition"

	16, 19-24, 27-30, 33-35, 38-39, 42-43, 46-48	
7,820,788; 7,923,536; 8,138,229	'788 patent: 10-12 '536 patent: 5, 6, 9, 10, 12, 13, 15, 16 '229 patent: 31-32, 44-45	"ratio (w/w) of albumin to the paclitaxel in the pharmaceutical composition"
8,138,229	'229 patent: 4-5, 9-10, 17- 18, 25-26, 36-37, 40-41,	"weight ratio of albumin to the paclitaxel in the pharmaceutical composition"

Dated: November 4, 2016

s/Liza M. Walsh

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CERTIFICATE OF SERVICE

I, Joseph L. Linares, hereby certify that I am an attorney at Walsh Pizzi O'Reilly Falanga LLP, counsel for Defendant Actavis LLC ("Actavis") in Civ. A. No. 2:16-cv-01925. On November 4, 2016, I caused a true and correct copy of Actavis' proposed terms for claim construction to be served by electronic mail upon the following attorneys of record for Plaintiffs:

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I hereby certify the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willingly false that I am subject to punishment

Dated: November 4, 2016

s/Joseph L. Linares
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EXHIBIT 6

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Subject: RE: ABRAxis BIOSCIENCE, LLC et al v. ACTAVIS LLC, 16-1925-JMV-MF

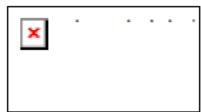
Counsel,

Pursuant to Local Rules 4.1 and 4.2, Actavis agrees that no claim terms need to be construed by the Court at this time, and therefore withdraws its preliminary disclosure of proposed claim terms for construction dated November 4, 2016. Actavis reserves all rights, however, to supplement its disclosures pursuant to the Local Patent Rules based on any positions Plaintiffs may take or any additional evidence that may be discovered in this action.

Regards,
Eimeric

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Subject: ABRAxis BIOSCIENCE, LLC et al v. ACTAVIS LLC, 16-1925-JMV-MF

Counsel,

At this time, Plaintiffs do not contend that any claim terms should be construed by the Court. Plaintiffs reserve their right, however, to supplement their disclosures pursuant to the Local Patent Rules based on Defendants' proposed claim terms and/or proposed constructions, or based on any additional evidence that they may discover in this action, including in response to Defendants' proposals and/or by proposing additional claim terms and/or constructions.

Regards,
Catherine

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EXHIBIT 7

No. 17-1120

United States Court of Appeals for the Federal Circuit

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY
Appellants,

v.

CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA INC.,
Appellees.

Appeal from the U.S. District Court for the District of Massachusetts,
Nos. 15-cv-10698-MLW and 16-cv-11117-MLW, Judge Mark L. Wolf

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March 7, 2017

U.S. Patent No. 6,284,471 Claim 1 (Appx197):

1. A chimeric antibody comprising at least part of a human immunoglobulin constant region and at least part of a non-human immunoglobulin variable region, said antibody capable of binding an epitope specific for human tumor necrosis factor TNF α , wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

U.S. Patent No. 6,790,444 Claims 1 and 2 (Appx293):

1. The chimeric antibody cA2.

2. A chimeric antibody comprising at least part of a human IgG1 constant region and at least part of a non-human immunoglobulin variable region, said antibody capable of binding an epitope specific for human TNF α , wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

U.S. Patent No. 5,656,272 Claims 1 and 7 (Appx380):

1. A method of treating TNF α -mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of an anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF-binding portion thereof and a human constant region.

7. A method of treating TNF α -mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.

U.S. Patent No. 5,698,195 Claims 1 and 6 (Appx472):

1. A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of an anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF antigen-binding portion thereof and a human constant region.

6. A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.

CERTIFICATE OF INTEREST

Counsel for Appellees Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira Inc. certify the following:

1. Full name of Party Represented by us:	2. Name of any Real Party in Interest not identified in response to Question 3:	3. Parent corporations and publicly held companies that own 10% or more of the stock in the party
Celltrion Healthcare Co., Ltd.	N/A	Celltrion Holdings Co., Ltd. (Korean corporation)
Celltrion, Inc.		Ion Investments B.V. (Netherlands corporation owned 100% by Temasek, an investment company based in Singapore)
		One Equity Partners IV, L.P. (Cayman Islands company 100% owned by JP Morgan)
Hospira Inc.		Pfizer Inc.

4. The names of all law firms and the partners or associates who appeared for the party now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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STATEMENT OF RELATED CASES

No appeal has previously been taken from the proceedings below.

In re Janssen Biotech, Inc., Appeal No. 17-1257 is related and has been designated as a companion appeal to this case in an order dated December 16, 2016, and entered in both dockets.

As explained in greater detail in this brief, in proceedings leading to this appeal, the district court invalidated claims 1, 3, and 5-7 of U.S. Patent No. 6,284,471 for obviousness-type double patenting for two independently sufficient reasons. *First*, the district court granted what is referred to in the record and Janssen's opening brief as the “*Gilead motion*”—finding those claims invalid for obviousness-type double patenting over U.S. Patent No. 6,790,444. *Second*, the district court granted what is referred to in the record as the “reexam motion” (so called because it relied on the same references as were at issue in the *In re Janssen* reexamination)—finding those same claims invalid for obviousness-type double patenting over both U.S. Patent No. 5,698,195 and No. 5,656,272.

In the proceedings leading to Appeal No. 17-1257, the Patent Trial and Appeal Board affirmed the Examiner's final rejection, after *ex parte* reexamination, of claims 1-7 (*i.e.*, all claims at issue in this appeal, and al-

so claims 2 and 4) for obvious-type double patenting. The affirmed rejections were based on the same reference patents as in the “reexam motion” at issue in this appeal. Thus, if this Court affirms the final decision in No. 17-1257, this appeal will necessarily be moot. *See Janssen Br.* 5. The claims and grounds of invalidity at issue in both appeals are shown in the chart below.

<u>Appeal</u>	<u>Reference Patents</u>	<u>'471 Claims Invalid for Obviousness-Type Double Patenting</u>
17-1120 (district court, this appeal)	“Gilead Motion”: No. 6,790,444	1, 3, 5-7
	“Reexam Motion”: Nos. 5,698,195 and 5,656,272	1, 3, 5-7
17-1257 (Board)	Nos. 5,698,195 and 5,656,272	1-7

PRELIMINARY STATEMENT

This appeal concerns the consequences that follow when a party repeatedly claims the same invention in multiple patent applications as part of a broad evergreening strategy to stifle competition. Janssen's '471 patent is one of more than *forty* patents from the same family. And Janssen *does not dispute* that the claims of the '471 patent are not patentably distinct over at least three of those patents. There are well-settled consequences to claiming the same subject matter over, and over again, and Janssen certainly knew that—or should have. It has been the law for more than 160 years that a patent grant is based on the inventor's implicit promise to the public to permit free use of the claimed invention—and obvious variants—once the patent expires. Thus, where an inventor holds multiple patents that are not patentably distinct, the earliest expiration date controls.

Against that backdrop, Janssen made calculated decisions when prosecuting its patents. Janssen accepted the benefits of its choices; it must also accept the costs. Instead, Janssen asks the Court to shift those costs to the public by carving out new exceptions to the doctrine of obviousness-type double patenting—exceptions that would require the Court to

repudiate the reasoning of prior decisions addressing the same issues raised here. There is no reason to re-write the law as Janssen asks.

First, in 2001, Janssen chose to file the application that led to the '444 patent. Because Janssen claimed a 1991 priority date, Janssen knew that any resulting patent would expire in 2011. And because of more than a century of obviousness-type double patenting precedent, Janssen knew that other patents it had that were not “patentably distinct” from the '444—but expired later—risked invalidation. Janssen nonetheless prosecuted its '444 patent to issuance, and benefited from having the '444 and '471 patents in force at the same time for several years. Janssen must accept the consequence of that choice: The public is now entitled to practice the inventions claimed in the '444 patent and the indistinct variants claimed in the '471 patent. Because the '471 patent—which Janssen concedes is not “patentably distinct” from the '444 patent—expires later, it is invalid for obviousness-type double patenting. *Gilead* and more than a century of precedent require that conclusion.

Second, when Janssen was prosecuting the '471 patent, it chose to file the application as a continuation-in-part—not a *divisional application*—in response to a restriction requirement. Again, Janssen accepted

the benefits of its choice: the continuation-in-part label allowed Janssen to add new matter to its application, which it did. However, Janssen's choice meant that it could not invoke 35 U.S.C. § 121's "safe harbor"—which protects only *divisional applications* filed in response to a restriction requirement. Yet, now that it serves Janssen's purposes to do so, Janssen tries to re-write history, asking this Court to save its patent from invalidity over the '272 and '195 patents on the basis of Janssen's later filings in the PTO. Those later filings are legally irrelevant here. In the face of similar tactics, this Court has repeatedly held that § 121 is strictly limited to patents resulting from applications actually filed as divisionals.

At the same time, Janssen asks the Court to ignore that it filed the continuation-in-part application that became the '471 patent on the same day as it filed the application that became the '272 patent. It does so in hopes that this Court will hold that its patents should be analyzed under the rarely-applied "two-way" test for obviousness-type double patenting, rather than the usual "one-way" test. But Janssen's same-day filings meant that it had no right to expect that patents resulting from those applications would issue in any particular order—and there is thus no reason to apply the "two-way" test. Moreover, based on undisputed facts, and as

the PTO has already determined, the PTO was not *solely* responsible for the '471 patent issuing after the '272 patent. As a matter of law, that means the “two-way” test cannot apply. In any event, the district court correctly found that the '471 patent is invalid over both the '195 and '272 patents, even under the “two-way” test.

In sum, no matter how it is approached, the '471 patent is invalid for obviousness-type double patenting—for the two independent reasons the district court gave, and for those the Board gave following the reexamination at issue in companion appeal No. 17-1257. (Affirming the Board’s decision would render this appeal moot. Janssen Br. 5.) For any or all of those reasons, the judgment should be affirmed.

STATEMENT OF THE ISSUES

Whether the district court’s judgment that the asserted claims of the '471 patent are invalid for obviousness-type double patenting should be affirmed for either or both of the following reasons:

1. The '471 patent’s claims are invalid over the '444 patent’s claims, where Janssen disputes only whether the holding of *Gilead* applies, on the ground that the '471 was a “transitional” patent—based on an application filed before the URAA went into effect—while the '444 patent is a post-

URAA patent.

2. The '471 patent's claims are invalid over the '272 and '195 patents' claims, where Janssen disputes the following:

a. Whether 35 U.S.C. § 121's safe harbor—which applies only to patents issued from divisional applications—applies where the '471 patent issued from a continuation-in-part application.

b. Whether invalidity of the '471 patent over the '272 or '195 patents should be assessed under the two-way test, which applies only if the PTO is solely responsible for the '471 patent having been filed before, but issued after, the reference patents—where the '471 and '272 patents' applications were filed on the same day and where Janssen's actions added more than a year to the prosecution of the '471 patent.

c. Whether, even if the two-way test applies, the '471 patent is nonetheless invalid, where the '471 patent discloses the same uses of its claimed composition that are claimed in the '272 and '195 patents.

STATEMENT OF THE CASE

This is an appeal from partial final judgment (certified for appeal under Rule 54(b)) that claims 1, 3, and 5-7 of U.S. Patent No. 6,284,471 are invalid for obviousness-type double patenting. Appx1 (judgment); Appx44-

61 (Rule 54(b) certification). Janssen Biotech, Inc. and New York University (“Janssen”) sued Celltrion Healthcare Co., Ltd., Celltrion Inc., and Hospira Inc. (“Celltrion”) under 42 U.S.C. § 262 and 35 U.S.C. § 271(e)(2)(C), alleging infringement of the ’471 patent and others. The ’471 patent is part of a family of more than 40 patents issued to Janssen. It claims antibodies including infliximab, an ingredient in Janssen’s biologic drug Remicade. Celltrion’s allegedly infringing product, Inflectra, is biosimilar to Remicade.

Two independent rulings support the judgment on appeal. Appx2-8. *First*, the district court granted Celltrion’s motion for summary judgment (referred to in the record as the “*Gilead motion*”) that the asserted claims of the ’471 patent are invalid for obviousness-type double patenting over U.S. Patent No. 6,790,444. Appx11-19 (opinion); Appx672-680 (oral ruling); Appx198-293 (’444 patent).

Second, the court granted Celltrion’s motion for summary judgment (the “*reexam motion*”) that the same claims of the ’471 patent are invalid for obviousness-type double patenting over U.S. Patent Nos. 5,698,195 and 5,656,272. Appx20-43 (opinion); Appx791-811 (oral ruling); Appx381-473 (’195 patent); Appx294-380 (’272 patent).

I. Legal Background

A. Obviousness-Type Double Patenting

Obviousness-type double patenting limits patentees “to one patent term per invention or improvement,” and enforces the inventor’s implicit promise to the public that, in return for the patent, the public will be free to use the invention after the patent expires. *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014). Thus, a claim is invalid for obviousness-type double patenting when it is not “patentably distinct” from (anticipated by, or obvious over), a claim in another, earlier-expiring patent held by a common inventor or owner. *Id.* at 1212-13; *In re Hubbell*, 709 F.3d 1140, 1146-48 (Fed. Cir. 2013).

Courts have applied the obviousness-type double patenting doctrine in this fashion for more than 160 years. See *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315, 317 (1866); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197-98, 202 (1894); *Gilead*, 753 F.3d at 1212 (collecting cases). The doctrine is older than the requirement of patent claims. See *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819) (Story, J.); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1372 (Fed. Cir. 2014) (discussing *id.*); *Gilead*, 753 F.3d at 1212 (same).

The doctrine is grounded in the Patent Act's text and public policy. *Abbvie*, 764 F.3d at 1372; *Longi*, 759 F.2d at 892. 35 U.S.C. § 101 provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, ... may obtain a patent therefor.” *Abbvie*, 764 F.3d at 1372 (original emphasis, quoting 35 U.S.C. § 101). “Thus, § 101 forbids an individual from obtaining more than one patent on the same invention, i.e., double patenting.” *Id.*

The policy is to enforce the public's rights under the bargain at the heart of the patent system: “in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of [the] patent term.” *Gilead*, 753 F.3d at 1212; *see also Singer Mfg. v. June Mfg.*, 163 U.S. 169, 185 (1896); *Miller*, 151 U.S. at 197-98. That bargain would be effectively circumvented, and a patentee's rights unfairly expanded at the public's expense, if an inventor were to hold multiple patents with different expiration dates, all on the same invention or obvious variants of it.

B. Terminal Disclaimers

In 1952, Congress passed 35 U.S.C. § 253, which allows patentees to disclaim the end of their patent terms. Patentees may avoid the effect of

obviousness-type double patenting by filing terminal disclaimers that cause otherwise later-expiring patents on obvious variations of an earlier-expiring patent to expire at the same time as the earlier-expiring patent.

Gilead, 753 F.3d at 1213-14; *Application of Braithwaite*, 379 F.2d 594, 601 (CCPA 1967).

C. The “Safe Harbor” of 35 U.S.C. § 121

Congress created a narrow exception to obviousness-type double patenting in 35 U.S.C. § 121’s third sentence.

The first sentence authorizes the PTO to issue restriction requirements during prosecution: when “two or more independent and distinct inventions are claimed in one application,” the PTO may “require the application to be restricted to one of the inventions.”

The third sentence “provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom), or based on applications or patents similarly derived from the same restriction requirement.” *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1360 (Fed. Cir. 2008). That sentence reads:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or

on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts *against a divisional application* or against the original application or any patent issued on either of them, if *the divisional application* is filed before the issuance of the patent on the other application.

35 U.S.C. § 121.¹

In practice, a restriction requirement typically informs the patent applicant how many separate inventions the PTO believes are in the application, and which claims correspond to each invention. MPEP § 817; *see also* Appx1809-1810. The applicant is asked to respond by “electing” one group of claims to continue prosecuting. The non-elected claims are withdrawn, but can be prosecuted in separate applications if the applicant desires. *See* 35 U.S.C. § 121; 37 C.F.R. § 1.142(b); MPEP § 821.02.

The Manual of Patent Examining Procedure defines three types of applications based on earlier applications—divisionals, continuations, and continuations-in part:

- **Divisionals:** “A later application for an independent or distinct invention ... *disclosing and claiming only subject matter disclosed in the earlier or parent application*, is known as a divisional application.” MPEP § 201.06. “A divisional application is often filed as a result of a restriction requirement made by the examiner.” *Id.*

¹ All quoted emphasis is added unless otherwise indicated.

- ***Continuations:*** “A continuation application is an application for the invention(s) disclosed in a prior-filed copending nonprovisional application,” whose “disclosure ... *must not include any subject matter which would constitute new matter* if submitted as an amendment to the parent application.” *Id.* § 201.07.
- ***Continuations-in-part:*** “A continuation-in-part is an application ... repeating some substantial portion or all of the earlier nonprovisional application *and adding matter not disclosed in the said earlier nonprovisional application.*” *Id.* § 201.08.

Although these may be filed in response to a restriction requirement, a restriction requirement is not a prerequisite. The main distinguishing feature of continuation-in-part applications—unlike divisionals or continuations—is that the applicant may add new matter not disclosed in the earlier application. *See Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1353 (Fed. Cir. 2009); *Pfizer*, 518 F.3d at 1359.

Section 121’s “safe harbor” thus operates as follows. If a patent applicant originally files an application that the PTO requires the applicant to split into multiple applications (the original and divisional applications), the directly-resulting patents cannot be used against each other for obviousness-type double patenting purposes.

This Court has emphasized that a “strict test” applies to the safe harbor in light of the public interest served by obviousness-type double patenting, and the “potential windfall ... to a patentee.” *G.D. Searle LLC v.*

Lupin Pharms., Inc., 790 F.3d 1349, 1354 (Fed. Cir 2015) (quoting *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003)). “[B]y its literal terms, [the safe harbor] protects *only* ‘divisional application[s]’ (or the original application) and patents issued on such applications,” and nothing more. *Pfizer*, 518 F.3d at 1360; *see id.* at 1362 (“The difference between divisional applications and CIPs … was well known at the time Congress enacted the 1952 Patent Act.”). Moreover, precedent requires “consonance”: “the applicant must maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement” to invoke the safe harbor. *Id.* at 1359.

D. Patent Terms and the URAA

The term of a U.S. patent is governed by 35 U.S.C. § 154, and begins when the patent issues. Before June 8, 1995, a U.S. patent generally expired 17 years from the date it issued. 35 U.S.C. § 154 (1988).

In 1994, Congress enacted the Uruguay Round Agreements Act (“URAA”), Pub. L. 103-465, 108 Stat. 4809, 4983 § 532 (1994). Following the URAA, a patent’s term still begins when it issues, but expires 20 years from the date the earliest application to which it claims priority was *filed*:

[The rights granted under a patent] shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under [various sections of 35 U.S.C.] from the date on which the earliest such application was filed.

35 U.S.C. § 154(a)(2) (1994).

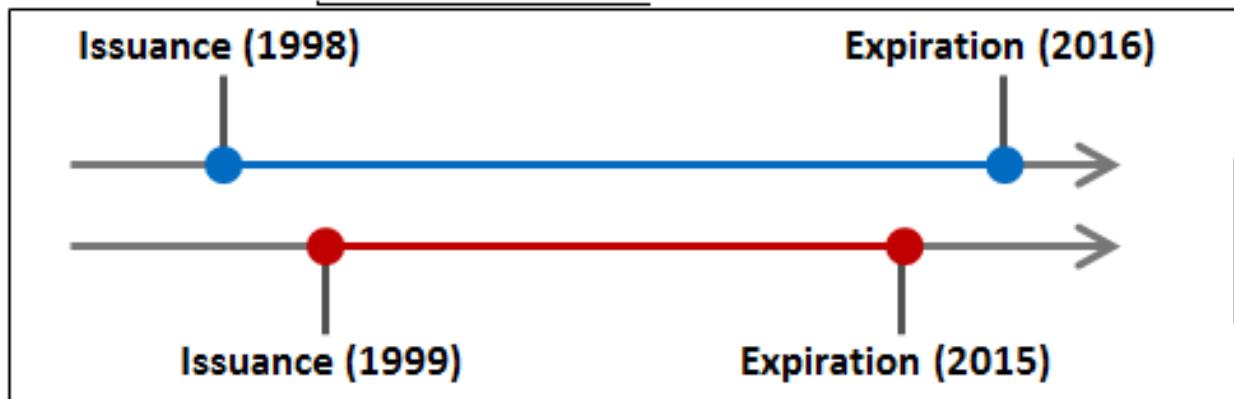
The URAA also contains a transition provision, which applies to the '471 patent. A patent from an application filed before June 8, 1995 expires on the later of **(a)** 20 years after the filing date of its earliest priority application (the post-URAA rule), or **(b)** 17 years from issuance (the pre-URAA rule). *Id.* § 154(c)(1).

E. This Court's Decisions in *Gilead* and *AbbVie*

In *Gilead*, the Court considered the continued vitality of obviousness-type double patenting after the URAA. 753 F.3d 1208. Before the URAA, nearly all U.S. patent terms were 17 years. If one patent issued before another, it expired sooner. A delayed issue date meant a later expiration date. Following URAA, however, **(1)** it is possible for one patent to both issue later and expire sooner than another, and **(2)** a delayed issue date means a delayed start to the patent term, but not a delayed end.

That was the situation in *Gilead*: the patentee asserted a patent that issued in 1998 and expired in 2016 (below, blue). The defendant ar-

gued that the patent was invalid for obviousness-type double patenting over a patent that issued in 1999 but expired in 2015 (below, red). 753 F.3d at 1210.



Thus, *Gilead* confronted the following question: “Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?” 753 F.3d at 1211-12. The Court “conclude[d] under the circumstances of this case that it can.” *Id.* at 1212. It canvassed the purpose and history of the obviousness-type double patenting doctrine at length, and concluded that the core of the doctrine was the inventor’s implicit promise to the public that it would be free to use the invention after the inventor’s patent expired. Although pre-URAA cases had discussed double-patenting in terms of both issue and expiration dates, “*the date that really mattered*,” *Gilead* explained, was the expiration date. *Id.* at 1215. “[T]he primary ill avoided by enforcement of the double pa-

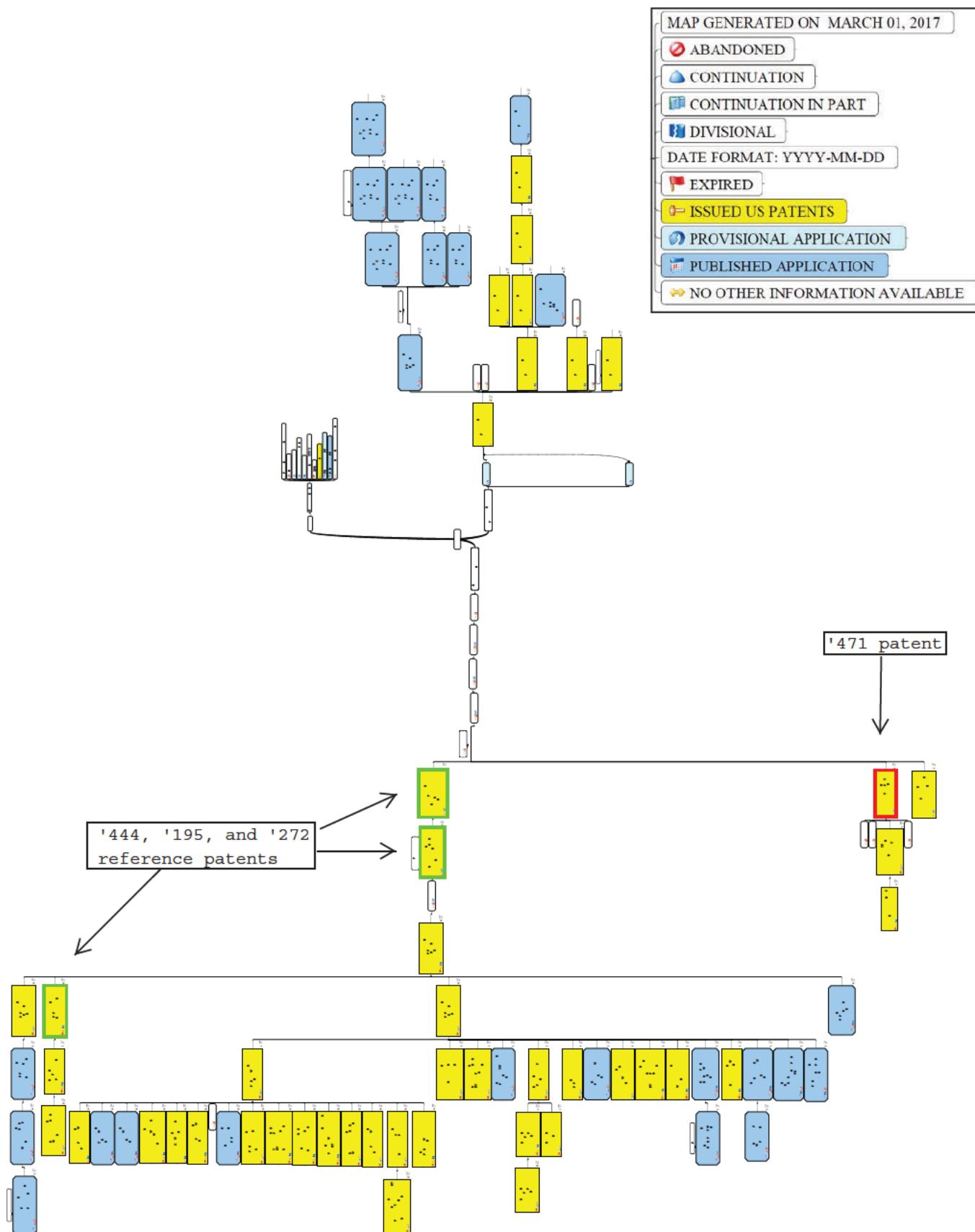
tenting doctrine is restriction on the public's freedom to use the invention claimed in a patent and all obvious modifications of it after that patent *expired.*" *Id.* (original emphasis). Thus, "[l]ooking ... to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting." *Id.* at 1216.

Four months later, the Court reaffirmed and clarified *Gilead*: We now make explicit what was implicit in *Gilead*: *the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates.*" *AbbVie*, 764 F.3d at 1374 (internal citations omitted).

II. Patents and Technological Background

This case involves multiple Janssen patents, all relating to chimeric (*i.e.*, derived from more than one animal species) anti-TNF α antibodies. "TNF α " is a type of tumor necrosis factor, Appx153 (9:45-51)—*i.e.*, a type of protein that causes inflammation and is implicated in diseases such as rheumatoid arthritis and Crohn's disease. Appx149(1:27-30, 45-47); Appx153(9:36-40); Appx165(34:3-25).

The '471 patent asserted here—and the '444, '272, and '195 reference patents—are all part of a family of more than 40 patents and 30 applications, all relating to chimeric anti-TNF α antibodies. The '471 patent's family tree is shown on the next page, with the '471 patent outlined in red, and the three reference patents outlined in green.



A. The '471 Patent

The '471 patent (Appx111-197) is titled *Anti-TNFA Antibodies and Assays Employing Anti-TNFA Antibodies*. It claims chimeric antibodies capable of binding an epitope (region) of human TNF α . Appx197(97:18-98:44). Claim 1 is illustrative:

1. A chimeric antibody comprising at least part of a human immunoglobulin constant region and at least part of a non-human immunoglobulin variable region, said antibody capable of binding an epitope specific for human tumor necrosis factor TNF α , wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

Appx197(97:18-25). SEQ ID NO: 3 and SEQ ID NO: 5 are amino acid sequences of regions of a cloned antibody called “cA2.” Appx152(7:20-25).

The patent is subject to the URAA’s transitional rule, 35 U.S.C. § 154(c)(1), for calculating its expiration date. The application directly leading to the '471 patent, U.S. No. 08/192,093, was filed in February 1994. Appx838. After more than seven years of prosecution, the '471 patent issued September 4, 2001, *id.*, and, standing alone, would expire September 4, 2018. Appx2.

B. The Reference Patents

1. The '444 Patent

The '444 patent claims chimeric antibodies, including cA2, capable of binding human TNF α . Appx293(109:17-25). The '444 patent's term is subject to the post-URAA calculation. It issued September 14, 2004 (after the '471 patent), Appx198, and expired July 11, 2011. Appx2. It is undisputed that the '471 and '444 patents' claims are not patentably distinct from each other. Janssen Br. 11 n.1; Appx12.

2. The '272 and '195 Patents

Like the '471 patent, the '272 and '195 patents are subject to the URAA's transitional rule for patent terms. Both issued in 1997 and expired in 2014.

Both patents claim methods of treating diseases with an anti-TNF chimeric antibody, including cA2. Claim 1 of the '272 patent claims a method of treating Crohn's disease. Appx380 (97:2-7). Claim 7 (among others) specifically claims use of the cA2 antibody:

7. A method of treating TNF α -mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.

Appx380(98:12-15).

The '195 patent resembles the '272 patent, but claims treatment of rheumatoid arthritis rather than Crohn's disease. Claim 1 provides:

1. A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of an anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF antigen-binding portion thereof and a human constant region.

Appx472(107:52-57). Claim 6 (among others) claims use of the cA2 antibody:

6. A method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2.

Appx472(108:57-59).

III. District Court Proceedings

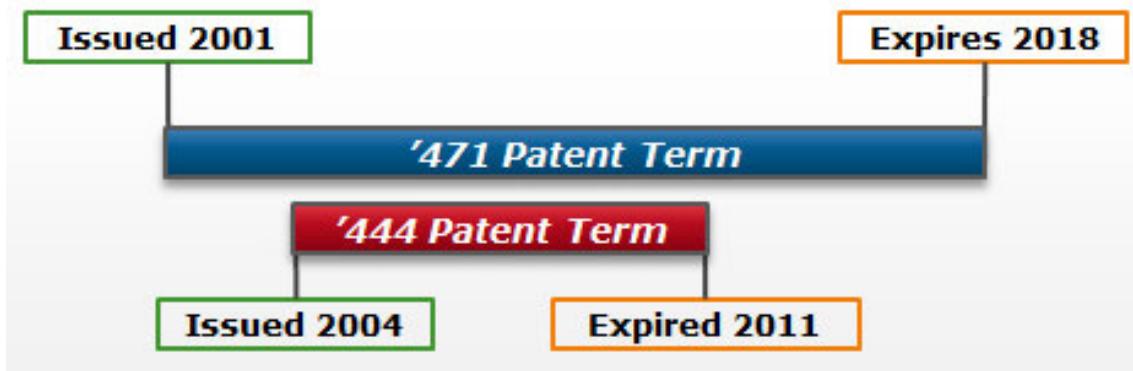
Janssen sued Celltrion for infringement of claims 1, 3, and 5-7 of the '471 patent. Appx83; Appx63. In two motions, which the district court granted, Celltrion sought summary judgment invalidating the '471 patent's claims' for obviousness-type double patenting on two independent grounds.

A. The “*Gilead Motion*” (Invalidity of the '471 Patent Over the '444 Patent)

Celltrion's first summary judgment motion argued that the '471 patent was invalid for obvious-type double patenting over the '444 patent.

Janssen conceded that the '471 patent's claims were not patentably distinct from the '444 patent's claims; it only disputed whether the '444 patent could properly serve as a reference for obviousness-type double patenting purposes.²

As explained above, the '471 patent issued from a pre-URAA application, so the patent's term started in September 2001 and would have run, standing alone, until September 2018 (17 years after issuance). Appx2. The '444 patent, however, issued from a post-URAA application, so it was issued in 2004 and expired in 2011 (20 years from 1991 priority date). *Id.*



Although this Court had held in *Gilead* and *Abbvie* that obviousness-type double patenting continues to apply following the URAA, Janssen's argument was that a patent with a term subject to the post-URAA calculation (the '444 patent) should not be used as a reference to invalidate a pa-

² Janssen does not contend that the “safe harbor” of 35 U.S.C. § 121 applies with respect to whether the '444 patent's claims render the '471 patent's claims invalid. *See* Appx519(15-17).

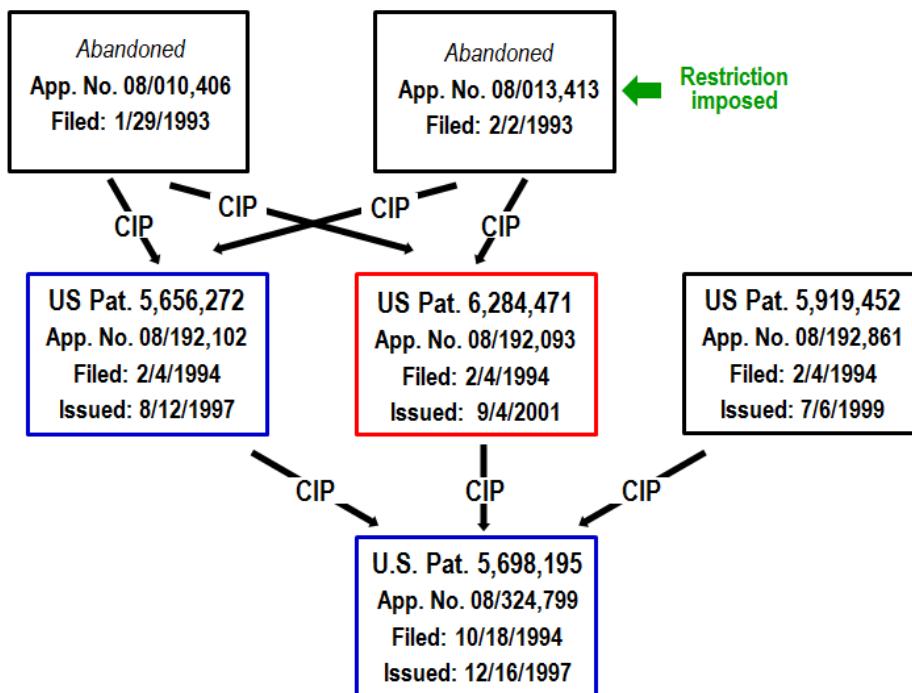
tent subject to the transitional rule (the '471 patent). Janssen tried to distinguish *Gilead* on the basis that the asserted patent and the reference patent in *Gilead* were both subject to the post-URAA calculation. The district court concluded that was a distinction without a difference, Appx13; Appx18, holding that the principles articulated in *Gilead* and 160+ years of obviousness-type double patenting precedent did not depend on whether the two patents were subject to the same rule for calculating expiration dates. The court noted that *Gilead* “essentially rejected [Janssen’s] argument here that the URAA manifests a statutory intent to provide patents emerging from applications filed before 1995 with at least 17 years’ protection despite the otherwise applicable judicial doctrine of obviousness-type double patenting.” Appx15 (citing *Gilead*, 753 F.3d at 1216); *see also id.* (the “URAA is silent on this issue”). And even though *Gilead* involved two post-URAA patents, Appx13, the court concluded that the “reasoning in *Gilead* indicates that the Federal Circuit would in this case find the ’471 patent obvious and invalid in view of the expired ’444 patent,” Appx17. The court thus concluded that the ’444 patent could be an obviousness-type double patenting reference to, and thus invalidated, the ’471 patent’s claims. Appx18.

B. The “Reexam Motion” (Invalidity of the ’471 Patent Over the ’272 and ’195 Patents)

In a second summary judgment motion, Celltrion contended that the ’471 patent’s asserted claims were also invalid for obviousness-type double patenting over the ’272 and ’195 patents. Appx20. The ’471, ’272, and ’195 patents issued from related continuation-in-part (“CIP”) applications. Their expiration dates are all subject to the URAA’s transitional calculation (the later of 20 years from the priority date or 17 years from issuance).

1. Prosecution of the ’471, ’272, and ’195 Patents

As shown below, the ’471, ’272, and ’195 patents all claim priority to two later-abandoned parent applications: U.S. Nos. 08/010,406 and 08/013,413. *See* Appx149(1:4-6); Appx332(1:5-7); Appx419(1:5-14).



The '413 parent application (top row, right) was filed in 1993 and contained 57 claims. Appx1809. The examiner concluded that it claimed five distinct inventions, and thus issued a restriction requirement. Appx1809-1810. In response, Janssen elected to continue prosecution in the '413 application of one invention, Appx4107-4116; Appx4207-4212, but later abandoned that application.

The '471 Patent. Janssen also filed Application No. 08/192,093, which led directly to the '471 patent. Importantly, Janssen filed that application as a *continuation-in-part* of the '413 and '406 applications (above, top row), because it contained new matter not disclosed in either parent. Appx149 (1:4-7); Appx2333 ¶93; Janssen Br. 15-16 (citing Appx4112). Prosecution continued on the '093 application for more than seven years. Janssen requested several extensions of time, Appx834; Appx1312-1331, declined an opportunity for the patent to issue in 1997, Appx2183; Appx2192-2196, and added more than a year to the prosecution by filing a notice of appeal it did not pursue. Appx2211-2214; Appx2914-2925. In 2001, the '093 application issued as the '471 patent. As noted above, standing alone, the '471 patent would expire in September 2018.

The '272 and '195 Patents. On the same day that it filed the application leading to the '471 patent, Janssen also filed the application leading to the '272 patent—again as a continuation-in-part of the '413 and '406 applications. Appx294; Appx332 (1:5-8). The '272 patent issued in 1997 and expired in 2014.

Months after filing the application leading to the '272 patent, Janssen filed the application leading to the '195 patent—as a continuation-in-part of three applications: (a) the application that led to the '272 patent, (b) the '093 application that led to the '471 patent, and (c) a third application. See Appx381; Appx419 (1:6-22). Like the '272 patent, the '195 patent issued in 1997 and expired in 2014.

2. The District Court's Resolution of the Reexam Motion

The district court concluded that the '471 patent's claims were invalid for obviousness-type double patenting over the '272 and '195 patents' claims.

First, the court rejected Janssen's argument that § 121's safe harbor precluded use of the '272 and '195 patents as reference patents against the '471 patent. Appx28-33. As explained above, § 121 provides a limited “safe harbor” for patents issuing from divisional applications filed in re-

sponse to a restriction requirement. *See § I.C, supra.* As just explained, however, none of the '471, '272, and '195 patents issued from divisionals resulting from a restriction requirement; all were filed as continuation-in-part applications. *See § III.B.1, supra.*

Janssen argued that the '471 patent should be treated as having resulted from a divisional application. Appx32-33. During a then-pending reexamination, Janssen noted, the PTO had “allowed an amendment to label the relevant application a divisional.” Appx32. The district court rejected Janssen’s argument, based on a close reading of this Court’s decisions in *Pfizer*, *G.D. Searle*, and *Amgen*, and the text of § 121. Appx28-33. Section 121’s safe harbor is limited to patents resulting from divisional applications filed in response to a restriction requirement—not the continuation-in-part applications Janssen chose to file. *See* Appx33 (Under *Amgen*, *Pfizer*, and *G.D. Searle*, “only patents resulting from applications filed as divisional are protected by the § 121 safe harbor.”). Janssen’s attempt at retroactively relabeling its patent was unavailing because, among other reasons, even if the patent were to emerge from reexamination relabeled as a “divisional,” the application would still not be a divisional “filed before the issuance of other relevant patents as required by § 121.”

Appx32. In *G.D. Searle*, this Court had rejected the same effort by a patentee to rewrite history with a post-issuance change of labels. Appx32.

Second, because the '471 patent falls outside § 121's safe harbor, the court considered whether its claims are invalid for obviousness-type double patenting over the '272 and '195 patents' claims. Appx33-42. An obviousness-type double patenting analysis typically requires only a "one-way" test, asking whether the challenged patent's claims would have been obvious over a reference patent's claims. Appx33-34 (citing *Hubbell*, 709 F.3d at 1149).

A "two-way" test applies in the "unusual circumstance" that "the PTO is *solely* responsible for the delay in causing the second-filed application to issue prior to the first." Appx34 (citing *Hubbell*, 709 F.3d at 1149). Under the two-way test, a challenged patent's claims are invalid only if they are not patentably distinct from the reference patent's claims *and vice-versa*. *Id.*

The district court concluded that the "one-way" test applies to the '272 patent vis-à-vis the '471 patent. Appx33-38. Because Janssen did not dispute invalidity under the one-way test, the court invalidated all the asserted claims on that basis. *Id.*

Finally, “in the interest of completeness,” Appx38, the court also applied the two-way test, and held that the ’272 and ’195 patents’ claims were obvious over the ’471 patent’s claims, and thus that the ’471 patent’s claims were invalid even under the two-way test. Appx39-42.

In sum, the district court concluded that all asserted claims of the ’471 patent are invalid for obviousness-type double patenting on two separate theories. The court also entered partial final judgment under Fed. R. Civ. P. 54(b). Appx44-61.

IV. The Concurrent *Ex Parte* Reexamination Leading to Appeal No. 17-1257

In the decision leading to companion Appeal No. 17-1257, the Board upheld an examiner’s final rejection of claims 1-7 of the ’471 patent for obviousness-type double patenting over the ’272 and ’195 patents. *Ex parte Janssen Biotech, Inc.*, Appeal No. 2016-6590, 2016 WL 6921121, at *1-2. (P.T.A.B. Nov. 14, 2016). Like the district court, the Board concluded that the ’471 patent does not benefit from § 121’s safe harbor. *Id.* at *3. The Board also found that Janssen “was responsible for significant delays in the prosecution of the ’471 patent,” and thus applied the one-way test for obviousness-type double patenting. *Id.* at *7-*14. Because Janssen did not dispute the obviousness of the ’471 patent’s claims over the ’272 and

'195 patents' claims under that test, the Board affirmed the examiner's rejection of claims 1-7 of the '471 patent. *Id.* at *14.

SUMMARY OF THE ARGUMENT

I. *The Gilead Motion.* This Court has for decades applied the obviousness-type double patenting doctrine according to a basic principle: when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious variants. Congress has never, including through the URAA, abrogated that principle. Janssen concedes that the '471 and '444 patents' inventions are not patentably distinct. Thus, once the '444 patent expired in 2011, the public was free to use the invention claimed in the '444 patent, as well as the concededly obvious variants claimed in the '471 patent. *Gilead's* clearly applicable reasoning, longstanding obviousness-type double patenting doctrine, and Janssen's choice to prosecute the '444 patent all demand that result.

II. *The "Reexam" Motion (involving the '272 and '195 patents).*

A. This Court has consistently held that § 121's safe harbor applies only to patents issuing from divisional applications. The '471 patent was filed as, and issued from, a continuation-in-part application, not a di-

visional. None of Janssen's arguments or *post hoc* attempts to restyle the '471 patent's application as a divisional can change that reality.

B. The one-way test governs whether the '471 patent is invalid for obviousness-type double patenting over the '272 and '195 patents. First, as to the '272 patent, the '272 and '471 patents resulted from applications filed on the same day, so the "unusual circumstance" in which the two-way test applies is not present. Because of the same-day filing, there is no issue of any patent application overtaking another. Second, as to both the '272 and '195 patents, as matter of law it cannot be said that the PTO was *solely* responsible for the '471 patent's delayed issuance. Because Janssen does not contest the invalidity of the '471 patent's claims under the one-way test, those claims are invalid for obviousness-type double patenting over *both* the '272 and '195 patents.

C. The district court correctly held that even if the two-way test applies, the '471 patent's claims are invalid. Janssen does not dispute that the '471 patent's claims are obvious over the '272 and '195 patents' claims. The '272 and '195 patents are also obvious over the '471 patent. The '471 patent's claims to chimeric antibodies encompass the cA2 antibody. Because those claims are to compositions, the '471 patent's specification can

be consulted in an obviousness-type double patenting analysis, and that specification discloses the use of the claimed antibodies (cA2, specifically) to treat rheumatoid arthritis and Crohn's disease. This is what the '272 and '195 patents claim. The '272 and '195 patents' claims are obvious over the '471 patent's claims, and thus the '471 patent's claims are invalid even under the two-way test.

STANDARD OF REVIEW

The district court's summary-judgment rulings are reviewed *de novo*. *Momenta Pharms., Inc. v. Teva Pharms. USA, Inc.*, 809 F.3d 610, 614-15 (Fed. Cir. 2015); *Maymi v. Puerto Rico Ports Auth.*, 515 F.3d 20, 25 (1st Cir. 2008).

ARGUMENT

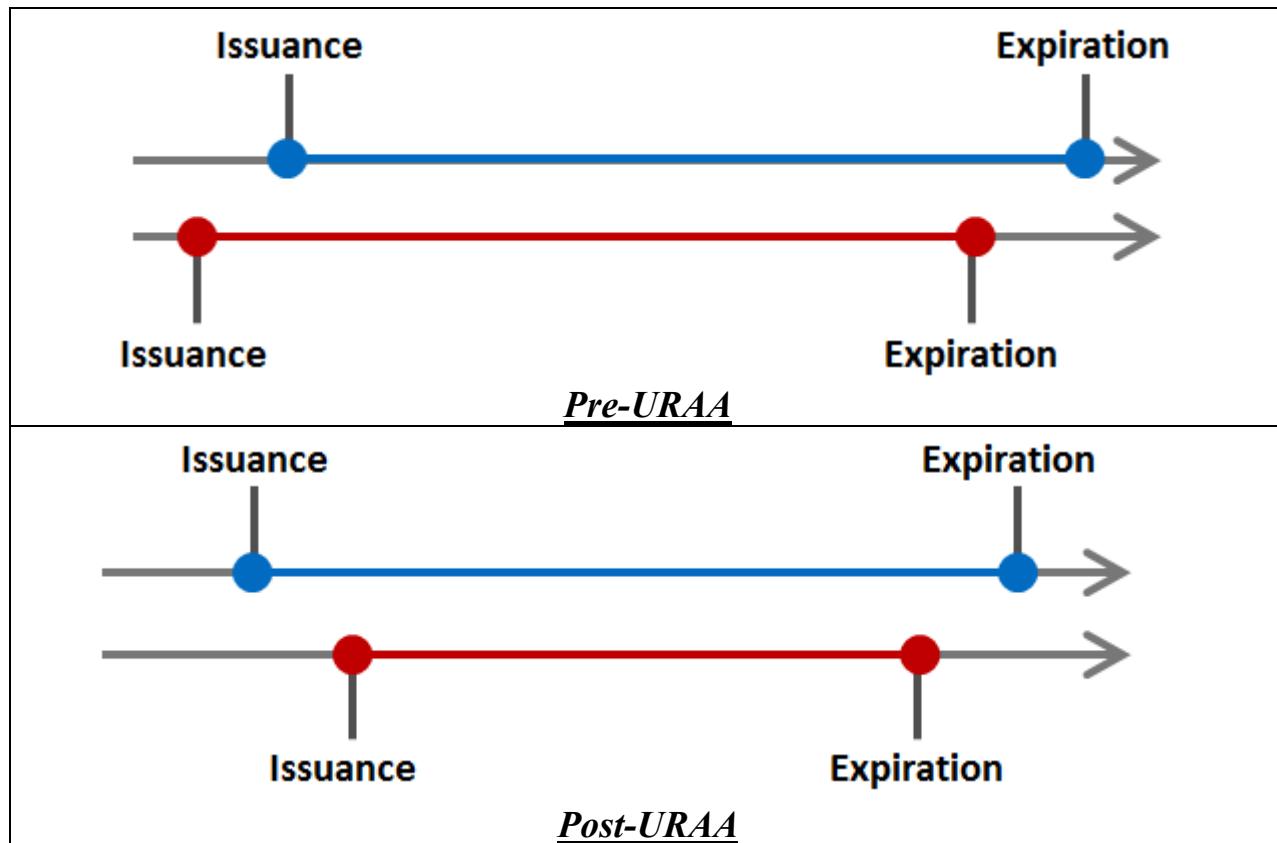
I. The earlier-expiring '444 patent's claims render the '471 patent's claims invalid for obviousness-type double patenting.

For more than 160 years, courts have applied the obviousness-type double patenting doctrine to enforce a “bedrock principle of our patent system”: “when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention.” *Gilead*, 753 F.3d at 1214.

Janssen's '444 patent expired in 2011. Janssen concedes that the '471 patent's claims are not patentably distinct from the '444 patent's claims. The district court thus correctly held that the public's right to use the invention of the '444 patent—and the obvious variants claimed in the '471 patent—began in 2011, and that the '471 patent was therefore invalid for obviousness-type double patenting. Janssen's contrary arguments rest on a clear misreading of *Gilead* and disregard for the principles underlying obviousness-type double patenting.

A. *Gilead* reaffirmed the longstanding principle that the inventor must permit the public to use his patented invention—and obvious variants—once the patent expires.

Before the URAA, nearly all patent terms were 17 years, and a patent that issued before another necessarily expired first. As shown below, the main relevant change brought about by the URAA was the possibility that one patent could both issue *after* and expire *before* a second patent.



In *Gilead*, this Court confronted the question, “Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent,” 753 F.3d at 1211-12, and answered in the affirmative. *Id.* at 1212, 1217.

The patentee (*Gilead*) argued—much as Janssen does here—that it would be unfair to the patentee and contrary to precedent to allow a later-issuing, earlier-expiring patent (red line in the bottom picture above) to be used as an invalidating reference patent. *Gilead* argued that what should be important is the date the first patent *issued*, and that obviousness-type

double patenting was only meant to protect against constructively extending the term of the first-*issued* patent. Specifically, Gilead argued the following:

According to these well-settled principles, then, it is the *issuance* of the first patent that signals the beginning of the term of protection for the patentee’s invention. ...

If a second patent subsequently issues to the same inventors, the question ... is whether the *second patent* provides an unjustified timewise extension of the right to exclude granted by the *first patent*.

Br. for Appellees, No. 13-1418 (ECF#26) at 25 (filed Sept. 16, 2013) (original emphasis), *available at* 2013 WL 5435227. Further, Gilead argued, where the term of one patent is entirely subsumed within another, there should be no role for obviousness-type double patenting, as the “full term” of the patentee’s rights—i.e., the full term of the *first-issued* patent—would have been the same with or without the later-issuing, earlier-expiring patent. *Id.* at 35; see *Gilead*, 753 F.3d at 1214 (noting Gilead’s arguments that the later-issuing, earlier-expiring patent “in no way extends the term of the exclusivity for the [other] patent,” and that the focus should have been “on the potential term extension for the [first-issuing, later-expiring patent] ... because [that patent] issued first.”).

This Court squarely rejected each of those arguments. The core of the obviousness-type double patenting doctrine, *Gilead* held, was the public's right to use the patented invention after the patent *expires*. Thus, the relevant question was not which of two indistinct patents *issued* first, but which one *expired* first. 753 F.3d at 1212 (“The prohibition against double patenting ... is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term ... The bar against double patenting was created to preserve that bargained-for right held by the public.”); *see also Singer*, 163 U.S. at 185. Thus, while it made sense in pre-URAA court decisions to refer to the respective patents' issue dates, that was because those dates “had previously served as a reliable stand-in for *the date that really mattered*—patent expiration.” *Gilead*, 753 F.3d at 1215.

The Court thus saw “little import ... in the fact that the [earlier-issuing, later-expiring] patent issued first.” *Id.* at 1214. Instead, it concluded that “it is the comparison of Gilead’s patent *expiration dates* that should control.” *Id.* at 1215. *Gilead* did not newly establish that principle; it merely affirmed that principle’s centrality to the obviousness-type double patenting doctrine. After discussing more than a century of precedent

from the Supreme Court and courts of appeals, *Gilead* explained, “[t]he double patenting doctrine has always been implemented to effectively uphold that principle,” *i.e.*, “that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably distinct modifications.” *Id.* at 1212; *see also Singer*, 163 U.S. at 185 (“It is upon this condition that the patent is granted.”); *Application of Robeson*, 331 F.2d 610, 614 (CCPA 1964) (similar).

Janssen concedes that the ’444 and ’471 patents are not patentably distinct. The ’444 patent expired in 2011. Thus, under longstanding precedent, the public’s right to use that invention—and the variants claimed in the ’471 patent—necessarily began in 2011. It is not delayed until the ’471 patent would otherwise expire.

B. This appeal does not differ materially from *Gilead*.

Janssen emphasizes that *Gilead* involved two post-URAA patents, whereas this case involves a pre-URAA patent (subject to the transitional rules) and a post-URAA reference patent. That is true as a factual matter, but is no basis for distinguishing *Gilead*. *Gilead*’s holding, and the principles it explained, apply equally here to invalidate the ’471 patent.

Because the URAA changed the relationship between issuance dates, expiration dates, and priority dates, the Court was required in *Gilead* to determine which of those dates was important for obviousness-type double patenting. *Gilead* reasoned—consistent with more than a century of precedent—that obviousness-type double patenting had always been “based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term.” 753 F.3d at 1212. Thus, the “date that really matter[s]” is the expiration date, *id.*, and “[l]ooking … to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting.” *Id.*

Those same principles dictate affirmance here. The ’444 patent expired in 2011, and to permit the ’471 patent to continue beyond that date would be inconsistent with Janssen’s promise to the public to permit free use of the ’444 patent and its obvious variants once that patent expired in 2011.

Janssen attaches significance to *Gilead*’s use of “under the circumstances.” *See, e.g.*, Janssen Br. 11, 36-37 (citing *Gilead*, 753 F.3d at 1212, 1217). But nothing in *Gilead* indicates that the Court limited its holding

to post-URAA patents invalidating other post-URAA patents. Neither paragraph using “under the circumstances” says a word about the URAA. *Gilead*, 753 F.3d at 1212, 1217. *Gilead*’s second use of “under the circumstances” may indicate that the Court meant to preserve the option of terminal disclaimers, but that cannot help Janssen here:

We therefore hold that an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent under the circumstances here. *In cases where such obviousness-type double patenting is present, a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent.* That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent’s term expires.

Id. at 1217. As *Gilead* explains, “using the expiration date as a benchmark in post-URAA cases of obviousness-type double patenting preserves the ability of inventors to use a terminal disclaimer of later-expiring patents to create one expiration date.” *Id.* at 1216. Here, Janssen has not exercised that option by disclaiming the ’471 patent’s term beyond the ’444 patent’s expiration date.

To the extent that Janssen would read anything more into *Gilead*’s use of “under the circumstances,” there is no basis for doing so. Judicial opinions are not to be read like statutes. *St. Mary’s Honor Ctr. v. Hicks*,

509 U.S. 502, 515 (1993). And, consistent with the federal judiciary’s duty to decide only “cases” or “controversies,” U.S. Const. Art. III, the holding of every judicial decision is in some sense “under the circumstances” of the case before the court. Here, the legally relevant “circumstances” are the same as those in *Gilead*.

Janssen’s selective quotation of other passages in *Gilead* likewise fails to show that Janssen’s pre- vs. post-URAA distinction makes a difference. In *Gilead*, this Court described pre-URAA patents’ terms as “inextricably intertwined with [their] issuance date,” which the Court concluded was “critical to a double patenting analysis” of such patents. 753 F.3d at 1214-15; *see Janssen Br.* 37 (quoting the same). But the Court did not thereby suggest that its reasoning would be inapplicable to pre-URAA patents. *Gilead*, 753 F.3d at 1214-15.

To the contrary, the Court used that description of pre-URAA patents to *reject* Gilead’s argument (akin to Janssen’s here) that earlier precedent forbade the use of a later-issuing patent as a reference to invalidate an earlier-issuing patent. *Id.* at 1214. The Court instead correctly recognized that its earlier decisions’ “focus on controlling the patent term of the later issued patents in those cases makes perfect sense: before the URAA,

later issued patents *expired* later.” *Id.* at 1215 (original emphasis). Thus, the Court concluded, “for double patenting inquiries” concerning pre-URAA patents, “looking to patent issue dates had previously served as a reliable stand-in for *the date that really matter[s]*”—expiration. *Id.*

Further confirming that *Gilead* does not support Janssen, *Gilead* noted that “the district court did not cite” *Ex parte Pfizer*, Appeal No. 2009-4106, 2010 WL 532133 (B.P.A.I. Feb. 12, 2010). *Id.* at 1211 n.2. (Janssen does not cite that case either). In *Pfizer*, as here, an earlier-expiring post-URAA patent was used as a reference to invalidate for obviousness-type double patenting a later-expiring pre-URAA patent. *Pfizer*, 2010 WL 532133, at *1-2, *15, *21-25. Although *Gilead* did not specifically comment on that posture, *Gilead* emphasized *Pfizer*’s recognition that “an extension of a patentee’s ‘right to exclude the public from practicing’ the invention in an expired patent” is “precisely what obviousness-type double patenting was intended to prevent.” 753 F.3d at 1211 n.2 (quoting *Pfizer*, 2010 WL 532133, at *21).

C. The URAA does not immunize pre-URAA patents from obviousness-type double patenting by post-URAA reference patents.

Janssen contends that an affirmance here would “jettison Congress’ judgment” in 35 U.S.C. § 154(c)(1) that pre-URAA patents’ terms “shall be the greater of 17 years from issuance or 20 years from filing.” Janssen Br. 42. That argument is largely rebutted by Janssen’s concession (on the same page of its brief) that Congress did not intend the URAA to “disturb the consistent application of the doctrine of double patenting.” *Id.* (quoting *Gilead*, 753 F.3d at 1216). Despite that concession, what Janssen seeks here is a categorical exception to the doctrine for the invalidation of pre-URAA patents by post-URAA reference patents. Such an exception would be inconsistent with the principles explained in *Gilead* and 160+ years of prior precedent.

First, the purpose and effect of the URAA’s transition rule should be apparent as a matter of common sense. Congress was changing the way patent terms were calculated, and needed to decide whether, at the time of the change, pending applications and in-force patents would be subject to the new rule, the old rule, or some combination of both. Congress chose a combination. Thus, 35 U.S.C. § 154(c)(1) provides that certain patents af-

fected by the transition will have a term “the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.” That is an ordinary transition rule, not an absolute statement that the term of an affected patent shall not only be a certain length—but shall *also* be immune from other laws such as obviousness-type double patenting. And if anything, the final five words of that passage—“subject to any terminal disclaimers”—refute Janssen’s argument. Janssen contends that § 154(c)(1) reflects Congress’ judgment that patents affected by the URAA are *absolutely* entitled to at least a 17-year term, notwithstanding other legal principles that might affect that term. But the text of § 154(c)(1) reflects not only that the term of transitional patents like the ’471 *is* subject to other legal principles—but that Congress specifically contemplated that such patents *would* be subject to obviousness-type double patenting. As *Gilead* explains, § 253’s terminal disclaimer provision was enacted specifically with obviousness-type double patenting in mind. 753 F.3d at 1212-13.

Second, Janssen’s attempt to glean an implicit immunity from obviousness-type double patenting from the URAA’s transition rule is inconsistent with Janssen’s concession that Congress did not intend the URAA

to “disturb the consistent application of the doctrine of double patenting.” Janssen Br. 42. It appears to be common ground between Janssen and Celltrion that Congress’ history of amending the Patent Act indicates acceptance of the obviousness-type patenting doctrine. Indeed, as this Court noted in *AbbVie*, the doctrine is grounded in part in the text of the Patent Act itself. 764 F.3d at 1372 (discussing § 101). Since the Supreme Court announced the double-patenting doctrine in *Suffolk*, Congress has amended the Patent Act at least a half-dozen times. *See Immersion Corp. v. HTC Corp.*, 826 F.3d 1357, 1361 (Fed. Cir. 2016) (collecting amendments). During that time, Congress has passed measures such as 35 U.S.C. § 253 (terminal disclaimers) and 35 U.S.C. § 121 (safe harbor for divisional applications), which implicitly recognize the vitality of the obviousness-type double patenting doctrine, and which affirm that doctrine’s core principle of enforcing the inventor’s implicit promise to the public to permit free use of his invention after his patent expires. *See Pfizer*, 518 F.3d at 1360-62 (legislative history of § 121); *Gilead*, 753 F.3d at 1213-14 (terminal disclaimers). Congress has never displaced or overruled the obviousness-type double patenting doctrine. If anything, that history reflects a consistent congressional understanding that the patent-term calculations of § 154

remain subject to other principles of patent law, such as obviousness-type double patenting.

Third, Janssen’s argument is inconsistent with *Gilead*’s holding that obviousness-type double patenting continues to apply even when a reference patent’s term is completely subsumed in the challenged patent’s term. Janssen repeats—six times—that “the only reason” the ’471 patent expires later than the ’444 patent is because Congress passed the URAA. Janssen Br. 2, 6, 11, 24, 31, 37. In *Gilead*, the patentee likewise argued, and the district court agreed, that the only reason the challenged patent expired later than the reference patent was “a result of changes to patent laws.” *Gilead*, 753 F.3d at 1211 (quoting district court). This Court *reversed*. Even if the URAA led to the situation of one patent both issuing before and expiring after another, the “core principle” of obviousness-type double patenting—the inventor’s promise to permit free use of his invention when the patent expired, *id.* at 1212—requires courts to continue to “[l]ook[] ... to the earliest expiration date of all the patents an inventor has on his invention.” *Id.* at 1216. That same principle requires affirmance here.

D. Janssen’s attempts to interject equitable or intent-based elements into the obviousness-type double patenting analysis fail.

Janssen’s last attempt to escape *Gilead* and more than a century of precedent consists of arguments that it would somehow be “unfair” to Janssen to apply obviousness-type double patenting here, because Janssen did not engage in “gamesmanship.” Janssen’s arguments are unsound.

First, obviousness-type double patenting is an objective test, much like obviousness. The inquiry comprises two steps: (1) construing the claims of the two patents, and (2) determining whether those differences render the claims patentably distinct. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384-85 (Fed. Cir. 2010). This Court and its predecessor have reiterated that a principal justification for obviousness-type double patenting is “to prevent unjustified timewise extension of the right to exclude granted by a patent *no matter how the extension is brought about.*” *Hubbell*, 709 F.3d at 1145; *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967-68 (Fed. Cir. 2001); *In re Van Ornum*, 686 F.2d 937, 943-44 (CCPA 1982); *Application of Schneller*, 397 F.2d 350, 354 (CCPA 1968).

Janssen relies heavily on *Gilead*’s statement that the patentee in that case had “crafted” separate chains of applications for the ’375 and ’483

patents. Janssen Br. 2, 10, 35, 37. But there was no finding of “gamesmanship” in *Gilead*, nor any implication that such a finding is a prerequisite to obviousness-type double patenting. Indeed, *Gilead* did not disturb the district court’s finding that the patentee had *not* engaged in gamesmanship. 753 F.3d at 1211.

To be sure, *Gilead* did recognize the *potential* for gamesmanship if the obviousness-type double patenting analysis were governed only by patents’ issuance dates. *Id.* at 1215-16. But to recognize that a rule may incentivize or deter gamesmanship is not the same thing as requiring a *finding* of gamesmanship before enforcing the rule. In *Warner-Jenkinson*, the Supreme Court rejected a similar misreading of *Graver-Tank* concerning the doctrine of equivalents: “*Graver Tank* refers to the prevention of copying and piracy when describing the benefits of the doctrine of equivalents. That the doctrine produces such benefits, however, does not mean that its application is limited only to cases where those particular benefits are obtained.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 34 (1997). Janssen’s argument relies on a similar misreading of *Gilead*.

Like obviousness-type double patenting, many rules in patent law serve purposes of conferring benefits and deterring harms, but are gener-

ally enforced without requiring proof that the harms or benefits appear in any particular case, and without delving into the litigants' subjective intentions. This is true of both statutory and judge-made rules. *See, e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (obviousness); *Warner-Jenkinson*, 520 U.S. at 36-37 (doctrine of equivalents); *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1426 (Fed. Cir. 1996) (experimental use exception).

There are, to be sure, doctrines such as prosecution laches, inequitable conduct, and indirect infringement that implicate questions of intent or misconduct resembling "gamesmanship." *See, e.g.*, *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760-61 (2011); *Therasense, Inc. v. Bechton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc); *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010). But Janssen cites nothing to indicate that obviousness-type double patenting is in that category, and as just explained, consistent precedent is to the contrary.

Second, Janssen argues that permitting it to enforce the '471 patent after the '444 patent expires is not "unjustified," "improper," or "undue." Those words appear in some decisions addressing obviousness-type double

patenting. *See, e.g., Schneller*, 397 F.2d at 354 (“fundamental reason” for obviousness-type double patenting doctrine is to “prevent[] the unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about”). In context, however, “unjustified,” “improper,” and “undue” merely express the conclusion that follows from a finding of obviousness-type double patenting: if a patent is invalid for obviousness-type double patenting, then it follows that the patentee is not “justified” in asserting the challenged patent after the reference patent expires. *See, e.g., Hubbell*, 709 F.3d at 1145; *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1379 (Fed. Cir. 2012); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005); *Eli Lilly*, 251 F.3d at 967-68; *Van Ornum*, 686 F.2d at 943-44; *Application of Thorington*, 418 F.2d 528, 537 (CCPA 1969).

In only one, narrow, obviousness-type double patenting decision does “justification” appear to do any meaningful work. In *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991), the Court found that a patentee was not “unjustified” in effectively extending its patent term where—solely due to the PTO’s actions beyond the patentee’s control, a broader patent issued after a narrower patent, and the later-issued broader patent’s claims encompassed

the earlier-issued narrow patent. *Id.* at 594-95. In other words, the effective extension of a patent term through multiple patents with different expiration dates is only ever “justified” when the PTO is solely responsible.

Janssen does not, however, argue that this case is similar to *Braat*. Instead, it argues that it was Congress’ enactment of the URAA that caused the ’471 patent to expire after the ’444 patent. Janssen Br. 2, 6, 11, 24, 31, 37. But it was Janssen’s decision to file for the ’444 patent in 2001 while claiming a 1991 priority date—not Congress’ enactment of the URAA in 1994—that led to the ’471 patent issuing before and expiring after the ’444 patent. And this Court has never recognized a change in law as justifying an exception to the consistent operation of obviousness-type double patenting. To the contrary, *Gilead* rejected such an argument. See § I.B, *supra*; 753 F.3d at 1211, 1214-17.

Finally, there is no unfairness to Janssen in any event. When Janssen filed for the ’444 patent in January 2001—years after the URAA’s enactment—it was almost certainly aware, or at least should have been, of the URAA’s effect on patent terms, and in particular that the ’444 patent would expire before the ’471 patent. Janssen nonetheless took a calculated risk in procuring the ’444 patent—not unlike what *Gilead* did in procuring

its second-issuing, first-expiring patent. During the '444 patent's term, Janssen benefited from having both patents in force at the same time. Any competitor would have to either design around or invalidate claims of both patents; not just one. Once the '444 patent expired in 2011, however, Janssen was required, under more than a century of consistent obviousness-type double patenting precedent, to make good on its implicit promise to the public—to permit free use of the '444 patent's invention and obvious variants. The district court appropriately held Janssen to that promise here. That ruling should be affirmed.

II. The '471 patent's claims are also invalid for obviousness-type double patenting over the '272 and '195 patents' claims.

The district court's determination that the '471 patent's claims are invalid for obviousness-type double patenting over the '272 and '195 patents' claims provides a second, *independent* basis for affirming the judgment.

A. Section 121's safe harbor does not apply.

As explained above, 35 U.S.C. § 121 “provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom), or based on applications or patents similarly derived from the same

restriction requirement.” *Pfizer, Inc.*, 518 F.3d at 1360. “[B]y its literal terms, [the safe harbor] protects *only* ‘divisional application[s] (or the original application) and patents issued on such applications.” *Id.* The safe harbor is subject to a “strict test” to avoid the “potential windfall … to a patentee.” *G.D. Searle*, 790 F.3d at 1354.

Janssen does not dispute that, in response to the examiner’s restriction requirement, Janssen chose to file the ’093 application (directly leading to the ’471 patent) as a continuation-in-part, *not* as a divisional. Janssen Br. 15. Nor does Janssen dispute that the application was properly labeled a continuation-in-part because it disclosed new matter not described in the ’413 application. *Id.* at 15-16; Appx2333 ¶93.

Thus, by its “literal terms,” and as consistently applied by this Court, § 121’s safe harbor cannot protect the ’471 patent. *Pfizer*, 518 F.3d at 1360-62. This Court has rejected, explicitly or implicitly, all of Janssen’s contrary arguments.

In *Amgen*, Amgen filed *continuation* applications following a restriction requirement. 580 F.3d at 1347-48. Amgen argued that the applications also met the requirements for divisional applications. Thus, because those continuation applications could have been labeled as division-

als, Amgen asked the Court “to look to [those] application[s’] substance—not [their] designation—to determine whether [they] qualifie[d] as … divisional application[s] under § 121’s safe harbor.” *Id.* at 1351. This Court rejected Amgen’s divisional-in-all-but-name argument, declining to depart from a “strict application of the plain language of § 121, which affords its benefits to ‘divisional application[s].’” *Id.* at 1353. It made no difference that Amgen’s applications “*could* have been filed as divisional applications.” *Id.* at 1354. What mattered was that they “*were filed* as continuation applications instead of divisional applications.” *Id.* Accordingly, the resulting patents “do not receive the protections afforded by § 121’s safe harbor.” *Id.*

Like Amgen, Janssen argues that the ’093 application was in substance a divisional of the restricted ’413 application, and thus the ’471 patent should benefit from § 121’s safe harbor. Janssen Br. 46, 48. But Janssen’s arguments are weaker than Amgen’s. In *Amgen*, the Court accepted that Amgen might have benefited from the safe harbor had it simply filed the same application as a divisional rather than a continuation. *Amgen*, 580 F.3d at 1353-54. Continuation-in-part applications like Janssen’s, however, by definition add new matter and cannot be labeled as

divisionals. MPEP §§ 201.06, 201.08. Here, it is only after a series of substantive amendments and maneuvers years after the fact that Janssen argues the '471 patent is *now* “a divisional in form as well as in substance.” Janssen Br. 46.

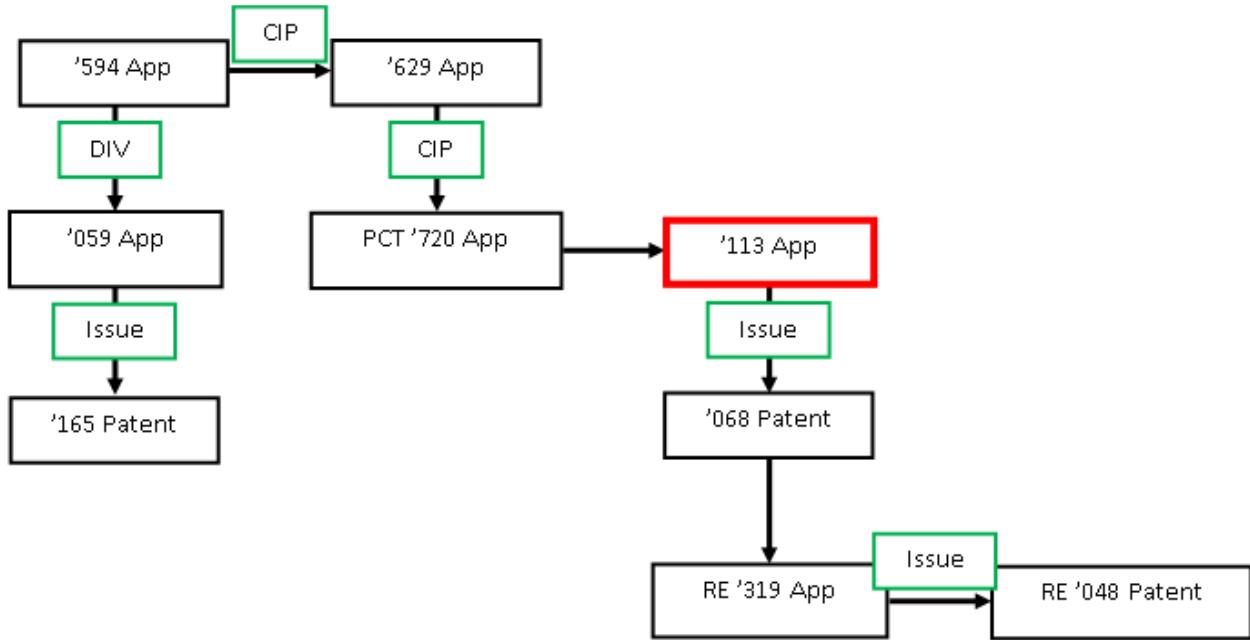
But Janssen’s procedural machinations to retroactively designate the '471 patent as issuing from a divisional application are also unavailing. During reexamination (ultimately leading to companion Appeal No. 17-1257), Janssen petitioned to amend the '471 patent by (1) deleting all but one paragraph of its specification and inserting the text of the '413 application’s specification, (2) deleting the priority claim to and incorporation by reference of the '406 application, and (3) designating the '471 patent a divisional of the '413 application. Appx4104. Although the Central Reexamination Unit’s director entered Janssen’s amendment—based on the understanding that 37 C.F.R. § 1.530 “demands entry of amendments when submitted in compliance with the rules and accompanied by the appropriate fees,” Appx4105—that makes no difference here.

As an initial matter, the amendments would not be legally effective unless and until the reexamination and appeals are complete and a reexamination certificate issues. *See* 37 C.F.R. § 1.530(k). The Board, howev-

er, has ordered the claims cancelled. In any event, even if treated as effective, the amendments cannot rewrite history to give Janssen the benefit of the safe harbor.

First, nothing in the Director's order indicates that Janssen's amendments were entered to invoke § 121's protection. Appx4105. The Board rejected any such implication, concluding that Janssen's amendments were entered for "procedural reasons," and "[t]he Director did not, in granting the petition, indicate that the effect of the amendment would be to confirm the '093 Application as a divisional." *Janssen*, 2016 WL 6921121, at *6.

Second, *G.D. Searle* conclusively rejects Janssen's argument. *G.D. Searle* and this Court's earlier decision in *Pfizer* involved a related group of patents, depicted below.



The patents and applications trace back to the '594 application (upper left), which was subject to a restriction requirement. *G.D. Searle*, 790 F.3d at 1351. Following that restriction requirement, the '629 application was filed as a continuation-in-part of the '549 application, and the '113 application (red) was later filed as a continuation-in-part of the '629 application. *Id.* at 1352.³ The '068 patent issued from the '113 application. *Id.*

In *Pfizer*, this Court concluded that the '068 patent was invalid for obviousness-type double patenting over the '165 patent (issued from a divisional of the '594 application), in critical part because the '068 patent is-

³ More precisely, the '113 application was the national-stage counterpart of the international-stage PCT '720 application, which was filed as a continuation-in-part of the '629 application. *G.D. Searle*, 790 F.3d at 1352.

sued from a continuation-in-part, not a divisional, application, and thus was excluded from § 121's safe harbor. *G.D. Searle*, 790 F.3d at 1352.

After *Pfizer*, the patentee filed another application (the RE '319 application) to reissue the '068 patent (ultimately as the RE '048 patent). *Id.* at 1353. The patentee then sued for infringement of the RE '048 patent, which the defendant again contended was invalid for obviousness-type double patenting over the '165 patent. *Id.* at 1353-54.

In prosecuting the RE '319 application, the examiner had allowed the patentee in *G.D. Searle* to (1) delete material from the '068 patent's specification not disclosed in the '594 application, (2) revise, add, and delete claims, and (3) designate the '113 application a divisional of the '594 application. *Id.* at 1353. Despite those amendments, this Court concluded that the RE '048 patent was not entitled to § 121's safe harbor because it did not issue on either the '594 application or a divisional of the '594 application. *Id.* at 1354. The critical break in the chain was the '113 application. *Id.* at 1354-55. Although later designated a divisional in the RE '048 patent, this Court concluded that the '113 application could not, in fact, be a divisional because it contained matter not present in the parent '594 application. *Id.* at 1355. The patentee's deletion of that new matter from the

RE '048 patent did “not retroactively alter the nature of the ’113 application.” *Id.*

The simpler but parallel facts here compel the same conclusion. As in *G.D. Searle*, Janssen cannot “retroactively alter the nature” of its application to invoke § 121’s safe harbor. Even setting aside that Janssen’s amendments are not legally effective, it remains a historical fact that *the ’471 patent did not issue on a divisional* of the ’413 application (or the ’413 application itself). *Id.* at 1354-55.

Janssen’s effort to distinguish *G.D. Searle* clearly misreads that decision. *G.D. Searle* acknowledged that permitting Pfizer retroactively to convert the ’113 application into a divisional of the ’594 application would be unfair to be public because Pfizer had previously enjoyed exclusivity over the ’068 patent’s claimed inventions, relying on the ’113 application’s new matter. *Id.* at 1355. The Court’s statement that the result avoided unfairness to the public does not invite an equitable balancing of the patentee’s interests against the public’s. The Court was construing a statute and applying the text as written, consistent with the “strict test” explained in earlier decisions. *Id.* at 1354 (quoting *Geneva*, 349 F.3d at 1382).

Finally, Janssen argues that the district court ignored five purported “fact issues about the safe harbor’s applicability.” Janssen Br. 49. Of those five, four (Nos. (1), (2), (3), and (5) at page 49 of Janssen’s brief) are not disputed issues of material *fact* at all, but legally irrelevant allegations by Janssen that, before this Court’s decisions in *Pfizer*, *Amgen*, and *Searle*, some practitioners and PTO employees may have believed that § 121’s safe harbor extended more broadly than this Court later determined that it did. Consistent with the duty of the judiciary to say what the law is, it is well-established that when a court “applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and as to all events, regardless of whether such events predate or postdate our announcement of the rule.” *Harper v. Va. Dep’t of Taxation*, 509 U.S. 86, 97 (1993); *Heartland By-Products, Inc. v. United States*, 568 F.3d 1360, 1365 (Fed. Cir. 2009); *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 & n.10 (Fed. Cir. 2008).

Janssen’s remaining “fact issue”—“concerning ... the absence of claims in the ’471 patent that are supported by additional matter not present in the ’413 Parent Application,” Janssen Br. 49—is likewise legally ir-

relevant. As discussed above, *Amgen* rejected that sort of divisional-in-all-but-name argument, ruling that section 121 must be applied as written to apply only to patents resulting from applications actually filed as divisionals, not applications that possibly could have been filed as divisionals.

Because Janssen filed the '093 application as a continuation-in-part, this Court's "strict test" bars the '471 patent's claims from § 121's safe harbor.

B. The one-way test for obviousness-type double patenting applies.

By default, this Court considers obviousness-type double patenting under a "one-way" test— asking whether the challenged claims are obvious over the reference patent's claims. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

In specific "unusual circumstance[s]," however, a "two-way" test applies, which asks whether the reference patent's claims are *also* obvious over the challenged patent's claims. *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009). The two-way test "is a narrow exception to the general rule of the one-way test." *Id.* It applies when a patent applicant files two applications in one order, but the resulting patents issue in the opposite order, and "the PTO is *solely* responsible for the delay in causing the sec-

ond-filed application to issue prior to the first.” *Id.*; *see also In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997); *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008). In that circumstance—where an earlier-filed application is essentially overtaken by a later-filed application at the PTO and issues second *solely* because of PTO delay, the obviousness-type double patenting inquiry compares the later-expiring patent’s claims to the first, *and vice-versa*. Whether the one-way or two-way test applies is a question of law, *Hubbell*, 709 F.3d at 1149; *Emert*, 124 F.3d at 1460, and depends on an applicant’s *responsibility* for prosecution delays, not its intent. *Fallaux*, 564 F.3d at 1317.

If the one-way test applies with respect to *either* the ’272 or ’195 patent, Janssen concedes that the ’471 patent is invalid. Janssen Br. 20 n.3.

1. The district court correctly held, consistent with *Berg* and the MPEP, that the one-way test applies to same-day filings.

The district court correctly concluded that the one-way test applies vis-à-vis the ’471 and ’272 patents. Appx35-38. The court recognized that “the two-way test [is] appropriate … in the unusual circumstance that the PTO is solely responsible for the delay in causing *the second-filed application to issue prior to the first*.” Appx35 (quoting *Berg*, 140 F.3d at 1437 and

citing *Hubbell*, 709 F.3d at 1159; *Fallaux*, 564 F.3d at 1313, 1316). Because the '471 and '272 patents' applications were filed on the same day, there was no "first-filed" or "second-filed" application—only two simultaneously-filed applications. In that circumstance, the MPEP provides—in a passage that remains unchanged to this day—that the one-way test applies. MPEP § 804 (July 1988) ("If ... both applications are filed on the same day, only a one-way determination of distinctness is needed ...") (citing *In re Berg*, 140 F.3d 1438 (Fed. Cir. 1998)). *Berg* explains that the two-way test applies "only ... when the applicant could not avoid separate filings, and *even then*, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application." 140 F.3d at 1435. Thus, "[t]he essential concern was to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *Id.* at 1432.

In other words, the "two-way" test was meant to address the situation of an applicant who files broader claims first and more specific claims second, with the reasonable expectation that the patents will issue in that

same order—but where, through no fault of the applicant, the order in which the patents issue is the reverse of the order of filing. But where, as here, a patentee files two applications on the same day, there is no issue of reverse-ordering, no reason to expect that the patents will issue in any particular order, and thus no reason to deviate from the traditional one-way test. As *Berg* explained, one who files two applications on the same day takes “a calculated risk” that either one could issue before the other. *Id.* at 1435. That is the risk Janssen took.

Janssen argues that the two-way test is “not intended to reward or punish order of filing.” Janssen Br. 52. But the issue is not one of rewards and punishments. The “one-way” test is the general rule, and the “two-way” test is a narrow exception into which Janssen does not fit.

Janssen suggests that the Court “should *treat* the application for the ’471 patent as having been filed” before the ’272 patent’s application because it has a lower serial number. *Id.* at 53. Janssen relies on *Immersion* (which Janssen concedes addressed a different issue). *Id.* at 54. Janssen waived this argument by failing to raise it below. But regardless, this Court has not required the PTO to enforce its rules and procedures by slicing time into smaller-than-a-day units. *Immersion* recognized the Patent

Act’s “pervasive[]” use of day-sized units for agency events. *Immersion*, 826 F.3d at 1362, 1365. The MPEP’s same-day rule of § 804.II(B)(2)(b) is an analogous determination—it clearly states that “[i]f ... both applications are filed on the same day, *only a one-way determination* of distinctness is needed” Having taken a calculated risk—the 50/50 chance that, all else equal, the ’471 and ’272 patents might issue in a different order than Janssen would prefer—Janssen must accept that the one-way test applies. There is no reason for this Court to revisit that settled principle.

2. As a matter of law, the PTO was not “solely” responsible for delays in the ’471 patent’s prosecution.

The district court correctly applied the rule of *Berg* and the MPEP to find that the one-way test applied between the ’471 and ’272 patents. However, this Court may also affirm for the separate reason that, as a matter of law, the PTO was not *solely* responsible for delays in prosecuting the ’471 patent’s application. *See Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013) (The “correctness of the decision appealed from can be defended by the *appellee* on any ground that is supported by the record.”) (original emphasis). That is an independent basis to find that the one-way test applies—not only for the ’272 patent but also the ’195.

“Whether a one-way or two-way analysis applies is a question of law that [this Court] review[s] without deference,” *Hubbell*, 709 F.3d at 1149. Even though the district court noted that “there *may* be a genuine factual dispute” about the PTO’s responsibility for delays in prosecution, Appx38, on the undisputed record of the ’471 patent’s seven-year prosecution, as a matter of law it cannot be said that the PTO was *solely* responsible.

In addition to obtaining numerous extensions, delays attributable to Janssen (or at least not solely to the PTO) include the following:

First, Janssen added more than a year to the prosecution by filing a notice of appeal with the Board, then changing its mind. Following a final rejection in May 1996, Janssen requested a three-month extension to file a notice of appeal. Appx2211-2212. In May 1997, Janssen requested a four-month extension to file its opening brief. Appx2214. But Janssen did not appeal, and instead filed an amendment in response to the May 1996 rejection, including adding claims 134 and 135 (now asserted claims 5 and 6). Appx2914-2925; Appx2337 ¶¶115-118.

Second, though the patent issued in 2001, Janssen forwent an opportunity to have the patent issue in 1997. In August 1997, the examiner rejected some claims, but concluded that others were allowable if rewritten.

Appx2183. Instead of seeking allowance, Janssen requested withdrawal of the finality of the August 1997 rejection, Appx2192; Appx2196, and sought a two-month extension to respond to it. Appx2216. As noted above, the patent did not ultimately issue until 2001.

As a matter of law, the PTO was not *solely* responsible for the '471 patent's delayed issuance. *Fallaux*, 564 F.3d at 1316. This Court has declined to apply the two-way test in similar circumstances where, as here, an applicant "received numerous time extensions in various filings," *compare Emert*, 124 F.3d at 1459-61 (patentee waited the full six-month statutory period to respond to office actions), *with* Appx2009; Appx2211-2212; Appx2214; Appx2216; and the claims asserted in litigation did not appear in prosecution until years after the patent's priority date. *See Hubbell*, 709 F.3d at 1149-50; *Fallaux*, 564 F.3d at 1317; *Basell*, 547 F.3d at 1376; Appx149(1:4-14) (earliest application in '471 patent's priority chain filed in 1991); Appx2914-2925 (Janssen adding claims 134 and 135 in May 1997); Appx2337 ¶¶115-118 (claims 134 and 135 correspond to asserted claims 5 and 6).

Further confirming that the PTO is not *solely* responsible for the delay in the '471 patent's issuance, Janssen's conduct would fail the test for

“reasonable efforts to conclude prosecution” under the PTO’s regulations addressing the analogous context of patent-term adjustments. Although not applicable here, the Patent Term Guarantee Act and implementing regulations are instructive on the general question of assessing responsibility for delays in prosecution. Some patents’ terms can be extended by adding days attributable to PTO delay during prosecution and subtracting days “during which the applicant failed to engage in *reasonable efforts to conclude prosecution.*” 35 U.S.C. § 154(b)(2)(C)(i). *See Pfizer, Inc. v. Lee*, 811 F.3d 466, 468-69 (Fed. Cir. 2016); 37 C.F.R. § 1.704. Under that standard, the PTO has concluded that taking longer than three months to (a) respond to an office action making a rejection or (b) file an appeal brief after filing a notice of appeal with the Board constitute failures “to engage in reasonable efforts to conclude prosecution”—both of which Janssen did here. *See 37 C.F.R. §§ 1.704(b), (c)(11); Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) (upholding 37 C.F.R. § 1.704(c)(8)). Given the PTO’s considered judgment that taking longer than three months is unreasonable delay, it follows that Janssen is at least partially responsible for the delays in the ’471 patent’s issuance.

In sum, because the undisputed facts show the PTO not *solely* responsible for delays in the '471 patent's issuance, Janssen is not entitled to the two-way test. And because Janssen does not dispute that the '471 patent's claims are invalid for obviousness-type double patenting over the '272 and '195 patents' claims under the one-way test, the district court's judgment should be affirmed for this additional reason.

C. Even under the two-way test, the '471 patent's claims are invalid.

Even if this Court concludes that there are genuine factual disputes concerning whether the one-way or two-way test applies, the district court correctly found that the '471 patent's claims are invalid even under the two-way test. Janssen does not dispute the obviousness of the '471 patent's claims over the '272 and '195 patents' claims; it only disputes whether the '272 or '195 patents' claims are obvious over the '471 patent's claims.⁴ They are, as the district court correctly held. Appx38-42. Janssen's contrary arguments are without merit.

First, Janssen's main argument is that the district court categorically should not have looked to the '471 patent's specification in its obviousness-

⁴ It is undisputed that if *either* the '272 or '195 patent's claims are obvious over the '471 patent's claims then the '471 patent is invalid under the two-way test.

type double patenting analysis. This Court has definitively rejected that argument. In *Basell*, this Court recognized “that certain instances may exist where a patent’s disclosure may be used.” 547 F.3d at 1378-79. And in *Geneva*, *Pfizer*, and *Sun*—which involved materially identical facts to this case—the Court did just that.

In *Geneva*, a claim to a method of inhibiting β-lactamase (a bacterial enzyme) using “clavulanic acid or a pharmaceutically acceptable salt thereof” was challenged for obviousness-type double patenting over the reference (Fleming) patent’s claim to “[p]otassium clavulanate” (a clavulanic acid salt). 349 F.3d at 1385. The Court “examine[d] the *specifications* of both patents to ascertain any overlap in the claim scope for the double patenting comparison.” *Id.* Because the Fleming patent disclosed potassium clavulanate’s utility—“administration to patients to combat bacteria that produce β-lactamase,” *id.* at 1385, the Court concluded that the challenged patent’s claims were invalid for obviousness-type double patenting over Fleming. *Id.* at 1375, 1377, 1385-86.

Critical to *Geneva* was the principle that governs here: “a claim to a method of using a composition is not patentably distinct from an earlier

claim to the identical composition in a patent disclosing the identical use.”

Id. at 1385-86. The Court explained:

It would shock one’s sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

Id. at 1386 (quoting *In re Byck*, 48 F.2d 665, 666 (CCPA 1931)).

Pfizer reiterated that principle, 518 F.3d at 1363 & n.8, and likewise concluded that challenged claims for methods of using a composition were invalid for obviousness-type double patenting over a reference patent’s claims to the composition—again, expressly relying on the reference patent’s disclosure of the *use* claimed in the challenged patent. *Id.* at 1363.

Sun again reaffirmed that same approach:

Thus, the holding of *Geneva* and *Pfizer*, that a “claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use,” extends to any and all such uses disclosed in the specification of the earlier patent.

611 F.3d at 1387; *see also id.* at 1388 (“we have expressly held that, where a patent claims a compound, a court performing an obviousness-type double patenting analysis should examine the specification to ascertain the coverage of the claim”).

Under *Geneva*, *Pfizer*, and *Sun*, the '272 or '195 patents' claims are not patentably distinct over the '471 patent's claims. Janssen concedes that claim 1 of the '471 patent encompasses the cA2 antibody. Appx1529 ¶13. And the '471 patent's specification describes the use of the claimed antibodies, including specifically cA2, to treat rheumatoid arthritis and Crohn's disease. Appx165-182 (33:52-34:25, 58:23-65:67, 66:20-68:20). The '272 and '195 patents, in turn, claim methods of using chimeric antibodies (including cA2) to treat Crohn's disease and rheumatoid arthritis, respectively. Appx380(97:2-98:16); Appx472(107:52)-Appx473(110:17). As a matter of law, those claimed methods of use cannot be patentably distinct from the '471 patent's claims to chimeric antibodies, where the '471 patent discloses identical uses for those antibodies. *Sun*, 611 F.3d at 1387-88; *Pfizer*, 518 F.3d at 1363 & n.8; *Geneva*, 349 F.3d at 1385-86.

Second, Janssen argues that *Geneva*, *Pfizer*, and *Sun* considered the reference patents' specifications only because the reference patents' claims did not recite any utility for their claimed compositions. Janssen Br. 58. Even accepting that reading would not help Janssen because the '471 patent's claims *also* do not recite any utility for its claimed compound. The "capab[ility] of binding an epitope specific to human necrosis factor TNF α ,"

Janssen Br. 59 (quoting Appx197), is a property of the compound—not a separate utility. The “utility” comes from administering the compound to a patient to treat Crohn’s disease or rheumatoid arthritis.

Regardless, Janssen’s reading is unsound, and essentially asks the Court to limit inconvenient precedent to its facts. No part of this Court’s reasoning in *Geneva*, *Pfizer*, or *Sun* relied on utility (or lack thereof) recited in the claims at issue. Indeed, none of the passages Janssen cites expressly states that the claims failed to recite a utility. Janssen Br. 58-59. In particular, *Sun* did not say so. *See* 611 F.3d at 1385. Janssen’s addition of “[only]” to its quotation of *Sun* misstates *Sun*’s reasoning. Janssen Br. 58.

Finally, Janssen asserts, with little explanation, that the two-way test cannot be applied without expert testimony, and that there is a “failure of proof” because Celltrion’s experts did not address the two-way test specifically. Janssen Br. 60-61. To the extent the argument is even developed enough to be preserved, *cf. SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006), it is wrong.

As an initial matter, the technology in *Geneva*, *Pfizer*, and *Sun* was at least as complex as here—*see Sun*, 611 F.3d at 1383-84 (gemcitabine

and cancer-treatment methods); *Pfizer*, 518 F.3d at 1357-58; *Geneva*, 349 F.3d at 1385—and the Court did not rely on expert testimony (or findings thereon). Rather, there, as here, the Court confronted the straightforward question of comparing a claim to a method of using a composition with an earlier claim to the composition in a patent that disclosed that same use. The record here allowed the district court to make that comparison and to conclude that the principle of *Geneva*, *Pfizer*, and *Sun* resolved the matter: “a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use.” *Geneva*, 349 F.3d at 1385-86. If there is any failure of relevant testimony, it is Janssen’s: its experts did not address the ’471 patent’s specification in analyzing the obviousness of the ’272 and ’195 patents’ claims, Appx3618-3651; Appx3653-3667—which, as explained above, is necessary to the inquiry under *Geneva*, *Pfizer*, and *Sun*.⁵

⁵ Janssen’s opening brief abandons its argument to the district court that a factual dispute existed over the obviousness of the ’272 or ’195 patent’s claims to *methods of using a species* over the ’471 patent’s claims to a *genus of compositions*. See Appx4507-4508. Janssen cannot revive that argument in its reply brief. *SmithKline*, 439 F.3d at 1319-21. The argument is meritless in any event. See *Basell*, 547 F.3d at 1377-78 (challenged species claim invalid over a reference patent’s genus claim).

Even under the two-way test, the asserted claims are invalid for obviousness-type double patenting. For that reason—or the '471 patent's claims' invalidity under the one-way test, or invalidity over the '444 patent's claims—the judgment should be affirmed.

CONCLUSION

The district court's judgment should be affirmed.

March 7, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

On March 7, 2017, this brief was submitted to the Court through the CM/ECF system, and thereby served on all parties.

/s/ William H. Burgess

**CERTIFICATE OF COMPLIANCE WITH
TYPE-VOLUME LIMITATION**

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7). According to the word processing system used to prepare this document, the brief contains 13,983 words.

/s/ William H. Burgess

EXHIBIT 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BEFORE THE HONORABLE MARK L. WOLF
UNITED STATES DISTRICT JUDGE

MOTTON HEARTING

August 16, 2016
10:02 a.m.

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1 P R O C E E D I N G S

2 THE COURT: Good morning. Would counsel please
3 identify themselves for the Court and for the record.

4 MR. DISKANT: Yes, Your Honor. I'm Greg Diskant on
5 behalf of the plaintiffs. And with me at counsel table is my
6 colleague Irena Royzman, also from my firm, Patterson Belknap,
7 and Barbara Mullin from Akin Gump. Sitting behind us is Eric
8 Harris, who is inside lawyer at Johnson & Johnson, which is
9 Janssen's parent, Jamison Davies from Patterson Belknap,
10 another colleague of mine, our tech support, Scott Burke, and
11 sitting behind us, because there's not enough room at counsel
12 table, Heather Repicky from the Nutter firm as our local
13 counsel.

14 THE COURT: Thank you.

15 MR. HURST: Your Honor, Jim Hurst. I'm here on behalf
16 of the defendants, Celltrion and Hospira. We also have some
17 Kline representatives here, Jeff Myers from Pfizer/Hospira and
18 David Kim from Celltrion. And I'll let each of the counsel at
19 counsel table introduce themselves, Your Honor.

10:09 20 THE COURT: Thank you.

21 MS. CUTRI: Good morning, Your Honor. Elizabeth Cutri
22 of Kirkland & Ellis.

23 THE COURT: Actually, could you each spell your last
24 names, please.

25 MS. CUTRI: Sure. My last name is C-u-t-r-i.

1 THE COURT: Thank you.

2 MR. KLEIN: Good morning, Your Honor. Chuck Klein
3 from Winston & Strawn. I'm sorry. It's K-l-e-i-n.

4 MR. HOANG: Good morning, Your Honor. Dan Hoang,
5 H-o-a-n-g, from Winston & Strawn.

6 MS. MARTIN: Good morning, Your Honor. Andrea Martin,
7 M-a-r-t-i-n, from Burns & Levinson.

8 MR. KELLY: Good morning, Your Honor. Dennis Kelly
9 from Burns & Levinson for the defendants in the case.

10:10 10 THE COURT: Okay. I'm Judge Wolf. You have me
11 outnumbered. I've gone almost 31 years without trying to make
12 a joke because everybody thinks they need to laugh at it.
13 Anyway. There are a lot of you.

14 As I understand, we're here today primarily for
15 hearings on the defendants' two motions for summary judgment
16 concerning the '471 patent and a *Markman* on hearing claim
17 construction with regard to the '083 patent. If there's
18 anything left when I decide those issues, which I aim to do
19 before these hearings conclude tomorrow or Thursday, there will
10:11 20 be a question of the trial date.

21 There's also a motion -- well, a stipulation that the
22 second case recently filed by the plaintiffs and assigned to
23 me, docket number 16-11117, should be consolidated with this
24 case, proceed on the same already-established schedule, and the
25 trial on liability and damages should or would be bifurcated.

1 I'm inclined to address that stipulation after I
2 decide the motions for summary judgment on the '471 and
3 construe the claim language in the '083 that's in dispute
4 because, as I said, that would affect as a practical matter
5 whether there's going to be anything left to consolidate the
6 second case with.

7 So subject to hearing from you, that's how I intend to
8 proceed. With regard to the agenda, your joint status report
9 is reasonable and helpful. I'll hear your argument first on
10:12 10 what's called the *Gilead* summary judgment motion concerning the
11 '471. I have immersed myself in that. I expect I'll be able
12 to decide that motion in the course of these hearings. We'll
13 proceed next to what the parties call the reexamination summary
14 judgment motion concerning the '471. I'm not quite so deeply
15 into that one.

16 Then we'll go to the claim construction of the '083
17 patent, which I've studied carefully. Then we'll go to the
18 plaintiffs' motion to expedite the trial, which I think would
19 be moot if I grant the motions for summary judgment and agree
10:13 20 with the defendants' claim construction on the '083. Then we
21 can talk about consolidating the two cases, which makes sense.

22 But is that the agenda you wanted to follow?

23 MR. HURST: Yes, Your Honor.

24 MR. DISKANT: Yes, Your Honor.

25 THE COURT: All right.

1 And about how much time do you think you would like to
2 present your views on each of the three substantive motions?
3 Just for planning purposes.

4 MR. HURST: I would think for each of the motions, at
5 least from our side in the neighborhood of 30 to 40 minutes,
6 maybe a little bit longer, depending on questions and so forth.

7 THE COURT: It will probably be longer.

8 MR. HURST: Okay.

9 THE COURT: Go ahead.

10:14 10 MR. DISKANT: Expecting that's what Your Honor would
11 say, I'm thinking more about an hour for each of ours, but
12 we're certainly prepared to respond --

13 THE COURT: That's fine. I'm sure you're, as usual,
14 very well prepared on this. Within those parameters I think we
15 should be able to get through the two motions for summary
16 judgment on the '471 today, hopefully including my decision on
17 the *Gilead* motion, and then we'll just keep going. But we have
18 tomorrow and, if necessary, Thursday.

19 All right. With regard to the motion for summary
10:15 20 judgment on the invalidity of U.S. Patent number 6,284,471, the
21 '471 patent, for obviousness-type double patenting, I have some
22 questions that you can address wherever they would -- the
23 responses would most naturally take your presentation.

24 As I said earlier, I've studied this. My tentative
25 view is that the defendants are entitled to summary judgment on

1 this issue. I don't view the question as decided by *Gilead*
2 because the facts are different. So I don't feel bound by the
3 decision, in other words -- do you know whether it's pronounced
4 *Gilead* or *Gilead*?

5 MR. HURST: *Gilead* I think is the way we pronounce it.

6 MR. DISKANT: That's what we're doing anyway.

7 THE COURT: The facts of *Gilead*, two patents had
8 applications after 1995, the effective date of the URAA. Here
9 one patent was applied for before and one afterwards. I
10 intended to ask you whether there were any other decisions that
11 have addressed this factual scenario. Yesterday the defendant
12 provided the *MLC* intellectual property decision which, as I
13 read it, came out in the way the defendant favors. But I want
14 to -- I'm interested in knowing whether there's any relevant
15 authority that wasn't cited.

16 I note that in *Pfizer* -- I'm sorry -- that in *Gilead*
17 at note 2 the Federal Circuit cited the Board of Patent Appeals
18 decision in *Pfizer*, which is analogous to the factual situation
19 in this case, and arguably indicates how it would decide this
20 case since it brought it to the parties' attention. But I'd
21 like you to address the implications of that footnote. I'm
22 interested in what's in the record or what inferences I should
23 draw as to why the plaintiffs sought the '444 patent for the
24 antibody when it already was covered by the '471 patent for the
25 genus that included that antibody. Was it because of a concern

1 that the '471 would be found invalid for obviousness double
2 patenting in view of patents different from the two at issue in
3 this case? Has the PTO now held the '471 invalid for this
4 reason, as the defendants assert in docket number 195 at page
5?

6 Again, to be transparent, it appears to me at this
7 point that the patentee made a judgment to try to strengthen
8 the patent claims knowing that if the '444 issued, it would
9 expire in 2011, not in 2018, like the '471 would if standing
10 alone, and that it was foreseeable that it might lose seven
11 years of patent protection, and it decided that it was
12 worthwhile to take that risk.

13 I don't know whether that's what the Federal Circuit
14 would call gamesmanship, but I'm having to essentially fill in
15 a gap in the statutory scheme and think about, you know, what
16 Congress would have done if it had addressed this issue as it
17 could have. And it seems to me that the statute manifests a
18 desire to be fair with regard to people's expectations. So I
19 wonder whether or why it would be unfair to the plaintiff to
20 find in effect that the patent protection expired for these two
21 closely related patents in 2011 in view of the -- particularly
22 in view of the Federal Circuit's reasoning in *Gilead*.

23 Then this may be more for the defendant. The
24 plaintiffs understandably argue that when they got the '471
25 patent they expected it provided protection until 2018 under

1 the URAA. Why shouldn't they get that? As I understand it,
2 the plaintiff does not contest for the purpose of this motion
3 or does not contend for the purpose of this motion that the
4 Section 121 safe harbor provision applies, but that should be
5 confirmed or clarified. In addition, it's my understanding
6 that the plaintiff concedes the inventions claimed in the '471
7 and '444 patents are not patentably distinct. Again, that
8 should be confirmed or clarified.

9 Someplace in all of that you've written and previously
10 argued, I was educated to understand, that Remicade generates
11 revenue of more than a billion dollars a year and may cost
12 patients or their insurers \$20,000 a year, but I don't know if
13 that's in the record before me for the purpose of this motion.
14 I think I asked you this previously, but has the PTO in the
15 reexamination held the '471 invalid for double patenting in
16 view of other patents than the '444?

17 So those are some of the questions.

18 It's the defendant's motion. I'm inclined to decide
19 it in favor of the defendant. You're probably intending to go
20 first?

21 | MR. HURST: I planned on it, Your Honor.

22 THE COURT: All right. Go ahead.

23 MR. HURST: As we did last time, I have some
24 PowerPoint presentations here.

THE COURT: Okay. I would have been disappointed if

1 you didn't.

2 MR. HURST: I don't know how many copies -- two,
3 three?

4 THE COURT: Two. We actually are probably going to
5 need a third to mark because my law clerk and I may mark these
6 up, so we'll make this PowerPoint presentation Exhibit A of
7 today's date. It's not evidence for the purposes of the motion
8 for summary judgment; however, it will illustrate what's being
9 shown and discussed.

10:24 10 MR. HURST: Do you need one?

11 THE COURT: No. That's okay.

12 MR. HURST: I'm sorry.

13 Your Honor, this is our motion over *Gilead*. Based on
14 your comments, I have some background information which I'll
15 hurry through.

16 THE COURT: Okay.

17 MR. HURST: And you tell me if it's too remedial,
18 given it does sound like you're pretty deeply into this.

19 This doesn't seem to be working. Turning it on would
10:25 20 help.

21 You indicated that there were factual differences
22 between *Gilead* and this case, and there are. We don't think
23 those factual differences are material, in part, Your Honor,
24 because all *Gilead* did is apply the bedrock principle of double
25 patenting to the post-GATT world.

1 THE COURT: GATT is the URAA?

2 MR. HURST: It is. It's simpler to say. Some people
3 refer to it as GATT and URAA. I tend to say GATT. So this
4 principle, it's a bedrock principle where patent system -- you
5 can find it literally in cases from the 1800s, that says that
6 when a patent expires, the public is free to use not only that
7 same invention but any obvious modifications. And *Gilead* said
8 that the double patenting doctrine has always been implemented
9 to effectively uphold that principle.

10:26 10 What that means is when you get a patent, you make a
11 deal, and the deal is when that patent expires, you will not
12 stand in the way of the public's right to practice that
13 invention or any obvious modifications with a different patent.

14 THE COURT: You'll get to this, but the plaintiff may
15 start by pointing out that, by its terms, the '471, which was
16 applied for in 1994, standing alone would expire in 2018.

17 MR. HURST: Right. That's true. And one of the
18 things -- and I will get to it, but as long as you raised it,
19 what plaintiffs are relying on is a statute that existed since
10:27 20 well before GATT. It actually has existed since -- is it 1961?
21 I have a slide for this. It says you get a 17-year term on a
22 patent. That has always been true, but that never insulates
23 patents from invalidity challenges, whether it's anticipation,
24 obviousness, lack of enablement or double patenting. The
25 statutory term of a patent is not some insurance policy against

1 an invalidity challenge. It's never been held to be. And it
2 wouldn't really make sense, right?

3 So here's the situation. As you noted, there's no
4 contention there's any patentable distinction between the two
5 patents. This is slide 3. Janssen has acknowledged that. So
6 our situation is on the bottom. The '444 patent term, it got
7 the term that it was entitled to get by law, and then it
8 expired in 2011. So you got another seven years.

9 The problem is that when it expired, according to a
10:28 10 principle that's existed since the 1800s, the public had a
11 right to practice the '444 patent invention and similar
12 inventions, but there's a patent standing in the way, the '471
13 patent. And literally since the 1800s, the law has been that
14 you can't do that; that second patent is invalid for double
15 patenting. It's an extra seven years beyond the statutory term
16 that by law the '444 patent was entitled to.

17 Just a little bit of background in how this all
18 arises, Your Honor, I think it might be helpful for a little
19 context, how the world changed after GATT, right? Before
10:29 20 GATT --

21 THE COURT: G-A-T-T, for the record?

22 MR. HURST: G-A-T-T, all caps.

23 So before GATT, it was, patents got 17-year terms from
24 the date of issuance, 17-year starts from the date of issuance.
25 So when courts were talking about double patenting, they often

1 talked about the earlier issued patent versus the later issued
2 patent. And it made sense because it was just a proxy for
3 expiration. If it was later issued, it had a later expiry. If
4 it was earlier issued, then you had an earlier expiry. So you
5 could find cases doing double patent analysis interchanging
6 those terms. They would sometimes talk about the
7 earlier-expiring invalidating the later-expiring. Sometimes
8 they'd say the earlier-issuing invalidating the later-issuing.
9 That was the issue in *Gilead*.

10:29 10 Should we be looking at issuance dates or expiry
11 dates? Because in the post-GATT world -- am I, like, too basic
12 for you right now?

13 THE COURT: No. It's okay. It's just confirming my
14 understanding. I know the Federal Circuit wrote about this in
15 *Gilead*. But it's okay.

16 MR. HURST: But here is the -- it can flip now. Under
17 the law, now it can flip. Why? Because you get 20 years from
18 your priority application, and the priority application might
19 have different -- there might be different priority
10:30 20 applications for the different patents.

21 And the patent term changes, too, because, say you
22 prosecute for five years, well, then you get a patent that only
23 lasts for 15 years. If you prosecute for ten years, you only
24 get ten years, or in this case of the '444 patent, prosecution
25 lasted 13 years. So Janssen is therefore entitled to seven

1 years. But you have this flip. So the question is raised.
2 What's the question? The question --

3 THE COURT: The prosecution, when you say it lasted 14
4 years, that's 14 years from 1991, but the application for the
5 '444 was filed in, what, 2001?

6 MR. HURST: Yeah, I think the one that led directly to
7 the '444 patent, but the priority application was back in '91.

8 THE COURT: Okay. Which is also the priority
9 application for the '471?

10:31 10 MR. HURST: Yes. They have the same priority
11 application. But here, what *Gilead* raises is a purely legal
12 issue in our view. This legal issue, Your Honor -- this is
13 actually a quote. This is slide 5. It's actually a quote from
14 *Gilead*, except I put in '444 and '471. "Can a patent," the
15 '444 patent, "that issues after but expires before another
16 patent, "the '471 patent," qualify as a double patenting
17 reference for that other patent?" That is literally the issue
18 that *Gilead* addressed and it applies directly here.

19 But here is what I think it turns on, and I think you
10:31 20 actually alluded to it, Your Honor. The question turns on
21 whether the standard rule from the 1800s applies to these three
22 different circumstances. We're in the third circumstance.
23 Everybody agrees that the standard rule applies to two pre-GATT
24 patents. Of course, it's been around since the 1800s.
25 Everybody agrees that that standard rule applies to two

1 post-GATT patents. That's *Gilead*.

2 So the argument that Janssen is raising is what about
3 one pre versus one post? I've read through the briefs. I'm
4 not seeing any principled reason why there would be an
5 exception here, but it would apply here in the second one.

6 THE COURT: Well, I frame this somewhat differently
7 perhaps than you do at least. I think this is a question of
8 statutory intent. So the GATT is a statute, right?

9 MR. HURST: Yeah.

10:32 10 THE COURT: And Congress and the president to some
11 extent but not completely addressed what to do in a
12 transitional period. So I think the statute said in 1995, for
13 patents where the application directly leading to the patent
14 was filed before 1995, that would be 17 years of patent
15 protection the way there had been previously.

16 For patents where the application was filed after
17 1995, in fact, the date of the GATT, it would be 20 years from
18 the priority date, right? So it would have been very easy if
19 Congress had addressed what happens in the factual scenario
10:33 20 here. The plaintiffs will argue we get the benefit of -- you
21 know, Congress intended that we would get 17 years on the '471,
22 and we should get 17 years.

23 MR. HURST: Think of it this way, Your Honor. All
24 you're doing is you're pointing out the way you calculate how
25 long a patent lasts. That's all. There were mechanisms for

1 counting how long a patent lasted prior to GATT. There's a
2 mechanism for calculating how long patents last after GATT.
3 There's a patent -- there's a time period for both. But none
4 of that changes the fact that double patenting is a separate
5 inquiry. It's always been a separate inquiry.

6 Patent term calculations never thwart double
7 patenting, never has. You would have to literally find that
8 Congress intended to overrule the doctrine of double patenting.
9 And there's really no basis for that.

10:35 10 In fact, literally this doctrine has been around since
11 the 1800s, and all *Gilead* said is, You know what? There's no
12 reason to change the doctrine. It still applies even in a
13 post-GATT world.

14 And here is what I mean. When you look at the *Gilead*
15 opinion itself, the way they frame the issue in their holding,
16 their holding, the way they frame the issue and their
17 reasoning, it all applies directly to this case notwithstanding
18 the factual distinction that you point out, Your Honor. Look
19 at the way they frame the issue.

10:35 20 THE COURT: Hold on a second. I'm just going to pull
21 out my copy of the decision.

22 Go ahead.

23 MR. HURST: I think I misspoke before when I said that
24 the 17-year term has been in a statute since 1961. It's
25 actually 1861. And despite that statutory 17 years, patents

1 have been invalidated for double patenting for over 150 years.

2 So the way they frame the issue, they frame it in a way that
3 applies directly to this case. "This appeal presents a narrow
4 question: Can a patent that issues after but expires before
5 another patent qualify as a double patenting reference for that
6 other patent?" That's literally the issue before Your Honor.

7 THE COURT: But the plaintiff is going to tell me that
8 you didn't read the next line, which says, "We conclude under
9 the circumstances of this case that it can, and therefore the
10 District Court erred in excluding the '375 patent as a
11 potential double patenting reference for the '483 patent." And
12 that's echoed in other places in the decision. They say "in
13 these circumstances," which I think means with two post-GATT
14 patents, and therefore the issue hasn't been -- the issue
15 presented by the facts of this case hasn't been decided by the
16 Federal Circuit in a way that I'm obliged to follow. It's an
17 open issue that I have to decide, subject to review.

18 Do you agree with that or do you --

19 MR. HURST: I disagree with the conclusion that the
20 phrase "under the circumstances" has anything to do with
21 whether the two patents are post-GATT there versus one
22 pre-GATT, one post-GATT.

23 THE COURT: So what do you contend "under the
24 circumstances" means?

25 MR. HURST: It's actually -- to me, it's just a

1 reference to the circumstances of this case where you have one
2 patent, the patent that's later-expiring, versus another patent
3 that's not patentably distinct being earlier-expiring.
4 Different circumstances could lead to different results.

5 For instance, a terminal disclaimer. A terminal
6 disclaimer would eliminate the double patenting. If the safe
7 harbor had been available, you might have a different
8 circumstance, or if you had a situation where you had an
9 argument for that rare two-way test, you might have a different
10:38 10 result. Nowhere in this decision that we see does the Federal
11 Circuit place any emphasis at all on the fact that both
12 patents' calculations for their terms happen to be post-GATT.

13 You said counsel would point out to me that I didn't
14 refer to the next sentence. He couldn't have said that because
15 I was about to get to it.

16 THE COURT: Okay. Good.

17 MR. HURST: So if you go to page 7, this is the
18 phrase. "We therefore hold that an earlier-expiring patent can
19 qualify as an obviousness-type double patenting reference for a
20 later-expiring patent under the circumstances here." The point
21 I was going to make is the one I just made, Your Honor, which,
22 there's literally nothing in the opinion that says, Well, we're
23 just talking about where one is pre-GATT and one post-GATT.
24 How do you know that? Look at the actual holding. I have it
25 on page 7. You have your case in front of you. I wish I had a

1 more precise -- it's 1217. What they say is, "Because the
2 obviousness-type" -- shall I read it? "Because the
3 obviousness-type double patenting doctrine prohibits an
4 inventor from extending his right to exclude through claims in
5 a later-expiring patent that are not patentably distinct from
6 the claims of the inventor's earlier-expiring patent." That's
7 a mouthful.

8 THE COURT: Hold on a second.

9 MR. HURST: Sure.

10:40 10 THE COURT: I don't see that on page 1217.

11 MR. HURST: My worry is that my point is for the
12 bottom quote. It's 1210. I apologize, Your Honor.

13 THE COURT: 1210. Okay.

14 MR. HURST: Okay. But you don't have to guess about
15 what caused the court to reach this conclusion, and there's
16 nothing saying it's pre-GATT -- special circumstance is one is
17 pre-GATT and one is post-GATT, because I'm not going to reread
18 it, but they tell you, because the obviousness-type double
19 patenting doctrine works as it does, we agree with *Natco* that
10:41 20 the '371 patent qualifies as an obviousness-type double
21 patenting reference. That first clause before the holding,
22 that applies directly here. We have a situation where an
23 inventor extended his or her right to exclude through claims in
24 a later-expiring patent that are not patentably distinct, that
25 would be the '471, from the claims of the inventor's

1 earlier-expiring patent, the '444.

2 THE COURT: I think your argument is that if we were
3 doing this before the GATT in 1995 and both patents had 17-year
4 life and the '444 expired first, then the '471 would be
5 invalid.

6 MR. HURST: Yes. And GATT doesn't change that. And
7 here is the thing that I guess jumped out at me. We've all
8 reread this opinion a bunch of different times, but because
9 it's so central, it's literally how you read this opinion, we
10:42 10 do think it's controlling, obviously. I'm not making any
11 secret of that. But look at some of the key things that the
12 court relied on. This is throughout the opinion. They are
13 saying that this prohibition against double patenting is based
14 on what they call a core principle, something the Supreme Court
15 established long ago, that "in exchange for a patent" -- this
16 is page 1212 -- "in exchange for a patent" --

17 THE COURT: Wait a minute. Which slide are you on
18 now?

19 MR. HURST: Slide 8.

10:43 20 THE COURT: Slide 8, okay.

21 MR. HURST: They call it "a core principle of our
22 patent system that the inventor must" -- now I'm reading yellow
23 highlighting -- "inventor must promise to permit free use of it
24 at the end of his patent term. The bar against double
25 patenting was created to preserve that bargained-for right held

1 by the public." It's actually a condition of getting a patent
2 granted, that you agree when your patent expires you're not
3 going to stand in the way of the public practicing your
4 invention with a different patent. You know what they cite for
5 that? This is the United States Court, United States Supreme
6 Court, 1896, that core principle of our system. This gets to
7 one of the issues that you raised when you were commenting on
8 the motion at the front end, Your Honor.

9 Janssen acted deliberately here. This was not a
10 secret to them, okay? They got the '471 patent in 2001. They
11 made a deliberate decision to accept the '444 patent in 2004.
12 It's not relevant to the motion about why they did that, just
13 not relevant. But you can surmise reasons one might do that.
14 They knew it was going to expire earlier. They certainly knew
15 about the standard case law they're saying about the condition
16 and the promise to allow your invention to become publicly
17 available and you wouldn't stand in the public's way. They
18 knew all of that. Why would they do it?

19 It might be -- I'm just speculating here, and I do not
20 think it's relevant or material to the motion, but it might be
21 simply that they thought this would provide them an advantage.
22 They may have thought that the '444 patent was a better patent.
23 It's a narrower patent. It didn't have the double patenting
24 invalidity problems that the '471 patent has. The Patent
25 Office at this point in time, just to confirm what you

1 believed, the Patent Office has in fact held the '471 patent to
2 be invalid for double patenting. Not over the '444 patent.
3 That's not before the Patent Office. That's only before you.
4 But over two different patents. The reexam patent we've been
5 talking about, '195, '272. Maybe that's why.

6 THE COURT: See, let me give you a chance to address
7 this.

8 MR. HURST: Sure, I want to, yeah.

9 THE COURT: In my present conception, the motive may
10:46 10 have some relevance. In other words, if a statute was passed
11 and it continued the historic 17-year length of patent
12 protection for patents filed before 1995, and I think Congress
13 wanted to create a bright-line 20-year test for all patents and
14 probably treat people who had the reasonable expectation that
15 they'd get 17 years when they invested before 1995 in getting a
16 patent, that protection, so I may hear, you know, Congress
17 didn't want to treat people in that class unfairly. But I
18 think this is, as I say, a matter of it's not so much inferring
19 statutory intent because they didn't address it.

10:47 20 MR. HURST: Didn't address that, right.

21 THE COURT: It's a gap. But then there are certain
22 canons of statutory construction. You look at the scheme. So
23 to me, whether this is fair or unfair to Janssen has some
24 relevance, but I did -- you know, I have thought about, they
25 could have had 17 years and they would have taken the risk that

1 the '471 would have been found invalid for some reason. Why
2 get the '444 which foreseeably would at least present this
3 issue and create uncertainty unless they felt they could get
4 something in return, and that is stronger patent protection for
5 a drug that at some point I've been told generates more than a
6 billion dollars a year in revenue.

7 MR. HURST: I think it's closer to four billion in the
8 United States.

9 THE COURT: Four billion dollars in revenue? Is that
10:48 10 in the record?

11 MR. HURST: I don't think it's the record. It's
12 close.

13 THE COURT: No. I said is it in the record of the
14 motion --

15 MR. HURST: Oh, is it in the record.

16 THE COURT: -- for summary judgment?

17 MR. HURST: I don't believe it's in the summary
18 judgment record but it's in the record elsewhere in other
19 motions.

10:48 20 Let me address that, and I have I guess two points --
21 three points. I'll make my quick ones first. My quick point
22 is, my first quick point is, they did this with their eyes
23 open. They knew what the law was; and whether they were hoping
24 that the law wouldn't apply post-GATT or not, they took that
25 risk for their own reasons, so they did it with their eyes

1 open.

2 My second point is, I think it would be a stretch to
3 say that Congress had any intent to do away with standard
4 double patenting law that's been around since the 1800s. And
5 that's all *Gilead* did. *Gilead* said we're going to apply a rule
6 that's existed forever to this post-GATT world.

7 Here is my third point, though, and I think it -- I
8 hope it addresses your question, your thoughts, pretty
9 directly. Doesn't your logic, wouldn't your logic take things
10 way too far? And I'll tell you why.

11 THE COURT: My logic is part of the reason I'm
12 inclined to rule for you, but go ahead.

13 MR. HURST: And I should -- the question you asked,
14 you said, Well, didn't Congress, when they said we're going to
15 give 17 years pre-GATT --

16 THE COURT: That's a -- okay. Go ahead.

17 MR. HURST: You're repeating, Your Honor; I understand
18 that. That same analysis, like Congress must have intended
19 that the 17 years would continue to be available regardless of
20 the calculation for patents post-GATT, that same argument was
21 available to *Gilead*, in the *Gilead* case. Why? Because
22 Congress created mechanisms for determining how long the
23 patents last. And the patentee in *Gilead* made a similar
24 argument. They said the world is different now post-GATT so
25 you should apply different rules. And so they're saying I had

1 an expectation in *Gilead* under the statute for calculating the
2 terms that my later-expiring patent was going to get a date
3 that was later-expiring. I had that settled expectation, given
4 what Congress did. And yet *Gilead* invalidated the
5 later-expiring patent for double patenting.

6 So it's the same type of rationale, right? There's no
7 greater reason to say that a patentee who relies on the
8 pre-GATT calculation has better protection against double
9 patenting than a patentee who relies on the post-GATT
10:51 10 calculation for how long their patents last. They both have
11 the same sort of argument that, gosh darn, I read the statute,
12 and I was entitled to believe my patent would last that long.
13 The easy response for that is, you got to read double patenting
14 cases to determine whether or not your patent is valid. You've
15 got to read anticipation cases, obviousness cases.
16 Calculations for patent terms never insulate or provide
17 insurance to a patent against an invalidity filing.

18 It's not just *Gilead*. Also, Your Honor, there are
19 later cases that confirm that *Gilead*'s holding is what it is
10:51 20 and that it should therefore apply. Because it's a really
21 simple, straightforward holding: Does your later-expiring
22 patent claim the same or similar invention. If so, if you
23 can't argue safe harbor, the patent is invalid, and they're not
24 arguing safe harbor. But this is the *AbbVie* case from the
25 Federal Circuit 2014.

1 THE COURT: Hold on a second. I've got that right
2 here, too.

3 MR. HURST: It's page 10 that I'm looking at of what
4 I'm looking at.

5 THE COURT: What slide, please?

6 MR. HURST: Slide 10.

7 THE COURT: Okay.

8 MR. HURST: So this was the situation in *AbbVie*, it
9 was actually related to patents owned by Janssen's predecessor,
10:53 10 Centocor. This is *AbbVie*'s summary of *Gilead*. So here is how
11 the issue arose. There was a double patenting challenge. It
12 was two post-GATT patents. What the patentee argued in the
13 case, Your Honor, was in the post-GATT world, we should have a
14 different rule. In fact, the patentee said, Let's do away with
15 double patenting altogether. What they argued is that
16 pre-GATT, there was a lot of opportunities for gamesmanship
17 because you had a greater ability to determine issuance dates
18 and therefore a greater ability to determine expiry dates.

19 The patentee has less control post-GATT because it all
10:54 20 turns on when they filed the application, so there's less
21 opportunity during prosecution to manipulate the expiration of
22 the patent. So what they argued is, in *AbbVie*, let's do away
23 with the double patenting altogether. And what *AbbVie* held is
24 we now make explicit what was implicit in *Gilead*. The doctrine
25 of obviousness-type double patenting continues to apply where

1 two patents that claim the same invention have different
2 expiration dates, and they're talking about the post-GATT
3 world. So they're literally saying what I believe *Gilead* said,
4 which is, We're not going to do away with the double patenting.
5 That standard black letter rule still applies into the future.

6 THE COURT: I don't recall the facts in *AbbVie*. Were
7 they again --

8 MR. HURST: Two post-GATT, two post-GATT.

9 I guess the point I'm trying to make is, the way the
10 Federal Circuit addressed the issue is literally, Should we
11 apply the old rule even after GATT, and the court said in
12 really clear terms, Yes, it will continue to apply where two
13 patents that claim the same invention have different expiration
14 dates. That is our situation. We have two patents that claim
15 the same or obvious variations with different expiration dates.

16 We cited a series of District Court cases to Your
17 Honor. They're not on-point cases, not at all, but we just
18 cite them to show -- until the one yesterday -- just to show
19 that people are reading *Gilead* the way that we're reading it.
10:55 20 The Federal Circuit has recently explained that expiration
21 dates, not issuance dates, are determinative, and that of
22 course is contrary to Janssen's argument here.

23 I'm sure you read the MLC case that we sent yesterday.

24 THE COURT: I read note 4. I didn't study the case.

25 MR. HURST: So note 4 is really the only part of the

1 opinion that addresses the issue that we are faced with here
2 before Your Honor. But the point here is the court here read
3 *Gilead* the exact same way as we do and actually addressed quite
4 specifically this contention that *Gilead* can be distinguished
5 based on the fact that there was one pre-GATT and one post-GATT
6 patent. I mean, the Northern District of Illinois -- sorry,
7 the Northern District --

8 THE COURT: California.

9 MR. HURST: -- of California, right. They refute this
10 in the ways that we're arguing. They say, No, no, look at
11 *Gilead*'s holding. It applies directly to both situations, both
12 two post-GATT or one pre-GATT and one post-GATT. They quote
13 *Gilead*, an earlier-expiring patent can qualify as an
14 obviousness-type double patenting reference for a
15 later-expiring patent. And they say the fact that the patent
16 in *Gilead* was governed by the URAA was not relevant to the
17 court's reasoning. *Gilead*'s holding was based on the principle
18 that -- and this is the principle I've been emphasizing -- when
19 a patent expires the public is free to use not only the same
20 invention claimed in the expired patent but also obvious or
21 patentably indistinct modifications.

22 That is our situation. The '471 is blocking the
23 public's right to practice the '444 patent. So there's a few
24 things that made me -- let me address some of Janssen's
25 particular arguments. One of the things that Janssen has

1 argued to Your Honor is, the differences in term -- this is
2 slide 12 -- the differences in terms between the '471 and the
3 '444 are due entirely to the change in the law, not any
4 improper actions by Janssen. That's the argument that they
5 made.

6 Your Honor, that is exactly the argument that the
7 patentee made in *Gilead*, and the District Court accepted it.
8 This is from the Federal Circuit's opinion, *Gilead*. "In the
9 District Court's view, any extensions of the patent terms at
10:58 10 issue were not unlawful because the extensions were not a
11 result of gamesmanship but instead were a result of changes to
12 patent laws."

13 So when Janssen says, Hey, there was a change in the
14 law; this isn't our fault; that's literally the position that
15 the *Gilead* patentee made and the position that the District
16 Court accepted, that it was really just a change in the law,
17 and of course the Federal Circuit reversed. So it's the same
18 argument.

19 Another thing that Janssen says to Your Honor is you
10:58 20 should look at the *Abbott* and *Brigham* cases. These were two
21 District Court cases decided before *Gilead*.

22 THE COURT: Right.

23 MR. HURST: And the Federal Circuit in *Gilead*
24 literally cited those cases. It said, relying on two District
25 Court cases, "the District Court below concluded that a

1 later-issued but earlier-expiring patent cannot serve as a
2 double patenting reference." That's the exact premise --
3 that's the exact holding that the Federal Circuit reversed in
4 *Gilead*. But here is -- to one of your other questions, Your
5 Honor, as a footnote, I believe that sentence, I believe this
6 sentence -- but I -- actually, I'm not 100 percent sure now --
7 there was a citation to *Pfizer*.

8 THE COURT: Hold on a second.

9 MR. HURST: Let me see if I'm right about that.

10:59 10 THE COURT: I think the citation to *Pfizer* is later.

11 MR. HURST: I'm being told, yes, it is later. It's
12 note 2.

13 THE COURT: Right. It is actually a note to --

14 MR. HURST: It is.

15 THE COURT: It is a note to the *Brigham* and *Abbott*
16 cases.

17 MR. HURST: I should have trusted my memory on that.

18 So anyway, look, there's no question there was
19 uncertainty about this before *Gilead* came out. I freely
20 acknowledge that. Folks were wondering whether post-GATT
21 double patenting would be applied in the same way. And two
22 District Courts said, No, it's not going to be. Obviously
23 *Gilead* disagreed with that.

24 But here is the part that -- right after citing those
25 two District Court cases, I think it's fair to say that the

1 Federal Circuit sort of chastised the District Court a little
2 bit. The District Court did not cite *ex parte Pfizer*.

3 THE COURT: Well, it may be that the parties didn't
4 cite it to the District Court. All right. I didn't view -- go
5 ahead.

6 MR. HURST: Your Honor, that was my reading, and it
7 might be wrong. But they said the District Court relied on
8 these two District Court decisions, but the District Court
9 didn't cite the contrary decision in *Pfizer*, and *Pfizer* goes
11:01 10 exactly our way in the exact same circumstances. There was one
11 pre-GATT patent and one post-GATT patent. And no reason to go
12 through it, but the Federal Circuit summarizes *Pfizer* in a way
13 that exactly repeats their reasoning for the overall decision.

14 THE COURT: What do you think the significance of that
15 is for this case?

16 MR. HURST: I think the significance of that is that
17 the Federal Circuit is saying in parallel, while they are in
18 this case dealing with two post-GATT patents, they're citing
19 with approval *Pfizer*, which deals with one post-GATT, one
11:01 20 pre-GATT, and they describe the court's decision in exactly --
21 it's a perfect summary of their own holding.

22 THE COURT: Well, I don't know if it's a perfect
23 summary of their own holding. It seems to me that it
24 communicates that the Federal Circuit was aware that the
25 factual scenario in this case could arise and was signaling,

1 even if it didn't have that factual scenario before it, that it
2 would decide the issue the same way.

3 MR. HURST: I think that's a fair reading of it, but I
4 think it's even more direct than that, just because the holding
5 was broad enough to cover this case. The issue presented was
6 broad enough to cover this case. All of its rationale is broad
7 enough to cover this case. Look how they describe *Pfizer*.
8 They describe it as if it's addressing the exact same issue as
9 they're seeing no distinction between *Pfizer*'s case and our
11:02 10 case.

11 They say, "According to the board, it was the patent
12 term and not the patent issue date that determines if a claim
13 qualifies as a double patenting reference. The later-expiring
14 patent in the board's opinion would impermissibly block the
15 public from practicing the invention." That's the argument
16 we're making here. Then they go on to say, "which is precisely
17 what obviousness-type double patenting was intended to prevent,
18 an extension of the patentee's right to exclude the public from
19 practicing the invention of an expired patent."

11:03 20 THE COURT: And the language comes from the decision
21 of the Board of Patent Appeals.

22 MR. HURST: True.

23 THE COURT: And it's quoted in *Gilead*.

24 MR. HURST: The Federal Circuit chose to quote a core
25 principle from the *Pfizer* Board of Patent Appeals decision that

1 they then themselves relied on to reach their own holding that
2 was perfectly consistent.

3 Here is another one of the things -- I said before,
4 when you read this opinion, all of its rationale and reasoning
5 and the bases for these opinions applies here as well. Here is
6 one of the points that the District Court -- I'm sorry, that
7 the Federal Circuit made in *Gilead*. They said, Look, if you're
8 telling me I ought to rely on issuance dates rather than
9 expiring dates, anomalies could occur. This is slide 16. "If
10 the double patenting inquiry was determined by issuance date
11 for post-URAA patents, there could be a significant difference
12 in the inventor's period of exclusivity over his invention and
13 its obviousness variants based on mere days' difference in the
14 issuance of several patents to the inventor." So what they're
15 pointing out is there are a lot of problems with looking at
16 issuance dates rather than expiration dates, and these
17 anomalies could occur.

18 Janssen is arguing to Your Honor to rely on issuance
19 dates for the '471 patent and that would create the same kind
11:04 20 of anomalies. Let me show you why. Here is what they said.
21 Janssen says the '471 patent issued first and that is the end
22 of the matter. Okay? So just adjusting the dates a little bit
23 to make my point, my top graphic here, it has the '471 issued
24 first by one day. So taking Janssen's rule, this seven years
25 of extra exclusivity doesn't amount to double patenting because

1 the '471 issues first by one day.

2 THE COURT: You mean if it straddled the --

3 MR. HURST: Well, it issued first before the '444
4 patent. So let's say the '444 patent issues one day after the
5 '471 patent, just one day, according to Janssen, that's all
6 you've got to look at. The '471 patent issued first, and that
7 is the end of the matter.

8 THE COURT: I think it's fair to say that the '471
9 issued first and was applied for before 1995.

11:05 10 MR. HURST: It doesn't matter when it was applied for
11 because, according to -- the '471 patent gets its terms based
12 on issuance date because it's pre-GATT. Janssen has argued on
13 issuance dates under this particular circumstances. So expiry
14 dates to pre-GATT, expiry dates to post-GATT, issuance dates,
15 that's their argument. You ought to look at the issuance date
16 for the '471 patent. That's their argument. They're literally
17 saying the '471 patent issued first, and that ought to be to be
18 the end of the matter.

19 To say it issued first by just one day, according to
11:06 20 Janssen, no double patenting. How about if it issues second by
21 one day? According to Janssen, that argument would be gone,
22 and there would be double patenting. The same anomalies that
23 the Federal Circuit was saying render it nonsensical or
24 unadvisable to focus on issuance dates would also apply here
25 because you see the same anomalies.

1 Just the last few slides. I know you've read the
2 opinion with care, so I'm not going to spend a lot of time on
3 this.

4 THE COURT: That's okay.

5 MR. HURST: One of the things Janssen is saying, it's
6 crystal clear from reading this opinion -- I'm not remembering
7 the exact quote, but they're saying it's super clear from
8 reading this opinion that the Federal Circuit was absolutely
9 limiting its decision to two post-GATT patents. But when you
11:07 10 read through this decision, there's nothing in there that
11 supports that proposition. They've decided the case on bigger
12 principles, principles that have been around for 150 years.
13 But look at some of the quotes that Janssen is relying on in
14 their sur-reply brief. They quote this sentence. You know
15 what, Your Honor? I'm getting a little bit ahead of myself,
16 and I apologize. So let me -- and I apologize for this, okay?

17 THE COURT: It's okay.

18 MR. HURST: Another argument is there was no
19 gamesmanship or abuse here. That's one of the arguments. No
11:08 20 gamesmanship or abuse. I've said before that's not a relevant
21 inquiry, whether there was or was not gamesmanship or abuse,
22 but that's the argument that Janssen is making. You should
23 find there's no gamesmanship and therefore no double patenting.
24 But that literally is what happened below in *Gilead*.

25 THE COURT: I know. In *Gilead* the District Court

1 relied on the fact there was no gamesmanship.

2 MR. HURST: Right.

3 THE COURT: Although gamesmanship is not a --
4 gamesmanship, the courts shouldn't endorse or abet something
5 that's inequitable. If somebody tries to -- I think this is
6 what I had in the *Columbia MDL Litigation*, where an application
7 was filed like the day before the effective date of the GATT
8 and got 17 years on a patent that everybody thought was
9 expired.

11:09 10 But here, as I say -- and I hope the plaintiff will
11 address it, and you address it. You know, it seems to me they
12 took a foreseeable risk when they got the '444, which they knew
13 would expire in 2011, and that is that the '471 would be deemed
14 to expire in 2011, too. And they evidently, you know, a big
15 sophisticated firm of good lawyers, you make a judgment that
16 it's worthwhile; it's worth the risk.

17 And I mean, it seems to me that in some respects the
18 risk has paid off because there's been five years of -- the
19 '444 expired in 2011. We're arguing about the '471 in 2016.
11:10 20 That's five years, if you're right that they've had revenues of
21 \$4 billion a year, that's \$20 billion during this period of
22 uncertainty.

23 I don't know -- my understanding of patent law is it's
24 intended to give inventors clear notice of what they can do and
25 what they can't do. Here is the invention. You can invent

1 around it or license it. Here is the expiration date, which I
2 thought the Federal Circuit in *Gilead* emphasized considerably.
3 We want a stable, clear expiration date. I think it's your
4 argument that in view of the historic doctrine of double
5 patenting, people reasonably skilled in the art would know
6 after 2011 we can do what would have violated the patent,
7 infringed the patent before 2011. Indeed, your client
8 evidently did that. You might argue that that it's in the
9 public interest to do that because you have competition.

11:11 10 MR. HURST: Yeah. I think that's a probably a good
11 way to summarize it. There was a foreseeable risk. People
12 knew the law and people knew what the expiration dates would
13 be.

14 I just want to address, though, this notion that there
15 has to be some inquiry into whether there was -- what people's
16 motives were, what their intent was, whether they were gaming
17 the system, whether they weren't. I think the *AbbVie* case
18 really puts this to bed a little bit. I mentioned this before,
19 but this is the case where Centocor argued let's do away with
11:11 20 double patenting altogether, and they said -- they argued to
21 the Federal Circuit there was no gamesmanship here. There's
22 less opportunity for gamesmanship post-GATT. So do away with
23 double patenting. They literally argued to do away with it
24 altogether. And their main argument was there was no
25 gamesmanship here, and there's no opportunity for gamesmanship

1 or less opportunity for gamesmanship post-GATT.

2 *AbbVie* rejected that. They said -- and this is slide
3 19, "but this argument about gamesmanship ignores another
4 crucial purpose of the doctrine. It is designed to prevent an
5 inventor from securing a second, later-expiring patent for the
6 same invention. That problem still exists."

7 So what they're saying is with or without
8 gamesmanship, you still face the problem of violating that
9 bargain, that bargain that when the first patent expires, you
11:12 10 can't use another patent to block the public's right to
11 practice the same or similar inventions.

12 Slide 21, I'm just getting to the point we talked
13 about before. "Janssen argues that the '471 patent is
14 expressly guaranteed by statute a 17-year term from the date of
15 its issuance." That's obviously not true. That 17-year term
16 has been around since 1861 and patents have been following
17 regularly since then.

18 There's a terminal disclaimer argument, Your Honor.
19 Would you like me to address that? It seems pretty
11:13 20 straightforward.

21 THE COURT: You can, but I actually -- sure, you can.
22 I thought it didn't have any relevance in this case. Go ahead,
23 address it, address it.

24 MR. HURST: One of the things that Janssen has argued
25 is we filed this sort of funny terminal disclaimer in

1 connection with the '444 patent. What they said is as long as
2 -- we will only enforce the '444 patent as long as it's
3 commonly owned with the '471 patent. That doesn't do away with
4 double patenting problems.

5 Double patenting -- the primary concern of double
6 patenting is this artificial extension beyond the patent's
7 expiry for the same or similar inventions. That's what *Gilead*
8 said. "A terminal disclaimer should be permissible to overcome
9 the prohibition of double patenting when it aligns the
11:14 10 expiration dates of an inventor's several patents that claim
11 mere obvious variations of the same invention to create a" --

12 THE COURT: What slide are you looking at?

13 MR. HURST: 22. The bottom line is you can avoid
14 double patenting simply by giving up on the extra patent term.

15 THE COURT: Right. The terminal disclaimer to be
16 effective, to have an impact in this case you argue, would have
17 had to provide that the '471 expire in 2011.

18 MR. HURST: Exactly. That's what *Gilead*, and many
19 cases recognize this; that in order to avoid a double patenting
11:14 20 problem you have to give your two patents the same expiration
21 date, such as, for all practical purposes, it creating a
22 situation where all the claims are in one patent. So that's
23 what you have to do, and they did not do it, intentionally, of
24 course, when they made that decision.

25 So this was getting to my point that I got ahead of

1 myself on a little bit. I think it's not -- Janssen, as they
2 argue that it's clear that this was only a case about two
3 post-GATT patents, they cite a bunch of snippets where the
4 Federal Circuit is referring to the URAA. But when you
5 actually read those quotes, none of those quotes even suggest
6 in my mind this notion that *Gilead* was placing any importance
7 whatsoever on the fact that one of the patents was -- both of
8 the patents were post-GATT.

9 Here is one sentence that Janssen relies on. "For
10 double patenting inquiries, looking to patent issue dates had
11 previously served as a reliable stand-in for the date it that
12 really mattered, patent expiration. But as this case
13 illustrates, that tool does not necessarily work properly for
14 patents in which the URAA applies."

15 That sentence applies here, too. Because here the
16 issue dates are not a reliable stand-in for patent expiration
17 dates. So the same concept that *Gilead* was talking about there
18 also applies here. Same thing. Here is another one. Janssen
19 relies on this quote. "Using the expiration date as a
20 benchmark in post-URAA cases of obviousness-type double
21 patenting preserves the ability of inventors to use a terminal
22 disclaimer of a later expiring patent to create one expiration
23 date."

24 Your Honor, that same concept applies here. If you
25 focus on expiration dates, it preserves the ability for

1 inventors to use terminal disclaimers to disclaim the later
2 term. And each sentence can apply here. So each sentence
3 they're relying on to say *Gilead* is different applies here 100
4 percent.

5 So let me summarize. I believe that *Gilead* just said,
6 simple as this, We're going to apply that century-old bedrock
7 principle into the future. That's the way I read *Gilead*.

8 That's the way I read *AbbVie*. That's the way the Northern
9 District of California last week read *Gilead*, too. To me,
11:17 10 there's no principled reason to draw an exception here,
11 particularly when Janssen invoked this bargain, this deal when
12 they took the '444 patent, and that deal, which has been around
13 forever, is that when it expires, they promise not to have
14 another patent or get another patent that would stand in the
15 way of the public's right to practice that '444 invention or an
16 obvious modification.

17 THE COURT: All right. Thank you.

18 MR. HURST: Can I just mention one quick thing? You
19 were asking for a cite for -- yes, you were asking for a cite
11:18 20 for where there's billions of sales. I have one. It's a
21 statement by Janssen, docket 200, and I believe it's paragraph
22 155.

23 THE COURT: Is that on this motion or another related
24 motion?

25 MR. HURST: It's on the related -- it's the reexam

1 summary judgment motion. "Billions in sales and most
2 successful product," I believe the quotes were.

3 THE COURT: Has somebody told me somewhere that
4 patients pay \$20,000 a year for this?

5 MR. HURST: I believe I did, and I think that's the
6 number I had at the forefront of my mind when we were last
7 before you, but I believe that's correct.

8 THE COURT: All right. We'll take a short break, and
9 you'll --

11:19 10 MR. HURST: Try to confirm.

11 THE COURT: One of the many lawyers here might look
12 for it. I don't know if that's in the record for the purposes
13 of summary judgment either.

14 Here, it's 11:20. We're going to take about a
15 five-minute break, maybe a few extra minutes, and then I'll
16 hear from Janssen.

17 Court is in recess.

18 (Recess taken 11:19 a.m. to 11:30 a.m.)

19 THE COURT: You may proceed.

11:30 20 MR. DISKANT: Thank you, Your Honor. We're switching
21 electronic systems, Judge. Thank you. We, too, have handouts.

22 THE COURT: I'll make the plaintiff Janssen's slides
23 on this Exhibit B.

24 MR. DISKANT: Thank you, Judge.

25 Let me start, if I may, with some general remarks in

1 light of some of Your Honor's general remarks and then turn to
2 the argument. First, I know from what you said just a few
3 moments ago and what you said at previous hearings that Your
4 Honor is quite interested, legitimately so, in low-cost
5 medicine to patients, and I completely understand that.

6 THE COURT: It's not -- let me say something else and
7 then you can finish what you were saying. It's not my -- I
8 don't have the power or the responsibility to decide what's
9 good policy. However, in discerning legislative intent, I
11:31 10 think whether something makes sense may have some relevance.
11 Anyway, go ahead. Say what you were going to say.

12 MR. DISKANT: I'm not quarreling with that. It is in
13 society's interest to make low-cost medicines available to
14 patients. That is an interest. But as Your Honor well knows,
15 the competing interest in the patent system is to encourage
16 innovation, risky innovation, and provide protection for it.

17 THE COURT: In fact, that's something I meant to ask
18 all of you. I'm going to ask it in the next motion. In 2000
19 in *Biogen v. Berlex*, before I started the *Markman* analysis I
11:32 20 said, you know, these are the goals of the patent system, to
21 provide inventors with sufficient incentive to invest,
22 sometimes make expensive risky investments, so give them
23 sufficient protection and then to give clear notice of what the
24 invention is so potential competitors can know what's protected
25 and what's not. And then after a reasonable period to give the

1 public the right to practice the invention and compete with the
2 inventor.

3 MR. DISKANT: Right.

4 THE COURT: Is that essentially still it?

5 MR. DISKANT: That's it, that's exactly right. The
6 only points I'd like to make with respect to that are that
7 developing drugs is extremely expensive. The average cost
8 today is \$2.3 billion. Johnson & Johnson invests \$9 billion
9 every year in R and D, most of which is wasted. So there's a
11:33 10 lot on the other side of the ledger if you want these medicines
11 which are revolutionary.

12 And I should tell Your Honor, because it so impressed
13 me when I first saw it, Remicade is a novel biological. I've
14 seen a video of the first patient with rheumatoid arthritis to
15 be treated with Remicade. And in the video, the woman staggers
16 down a staircase, holding on. She's so crippled, she can
17 barely move. Three months later, she literally dances down the
18 stairs and does a pirouette. That's what this drug can do.
19 That's why it's been so successful.

11:34 20 It's expensive because the R and D is expensive, but I
21 think Your Honor also needs to know, and it is in the record,
22 that when competition comes, the savings are not by and large
23 going to be felt by patients. They're going to be felt by
24 insurance companies. Because the co-pay isn't going to change,
25 the insurance companies will save the benefit, and for people

1 who are uninsured, Johnson & Johnson has always made various
2 programs available to get the drug to people who need it. So I
3 know that cost is a large number, but it's just not correct to
4 think about this as a savings going to go to patients. I know
5 in the end that doesn't have any bearing --

6 THE COURT: Well, we live in a country that, you know,
7 sort of generally believes in price competition ordinarily.

8 MR. DISKANT: Mm-hmm. I completely agree. I'm just
9 commenting on --

11:35 10 THE COURT: No. Certainly as a citizen, I think also
11 a judge, I'm very interested to hear and be reminded of some of
12 it. Thank you.

13 MR. DISKANT: That's just true. A couple of other
14 just introductory comments that bear on questions that Your
15 Honor asked earlier today. This is not a safe harbor case. We
16 are not arguing in this case that the '444 is patentably
17 distinct from the '471. So those issues aren't here.

18 Lastly, Mr. Hurst said it, but I want to say it also,
19 the Patent Office has not found the '471 patent invalid over
11:35 20 the '444 patent. That issue has not been raised in the reexam.
21 That has never been found.

22 THE COURT: What I understood was it so far found the
23 '471 invalid as compared to the patents I'll be looking at in
24 the reexam issue. Is that correct?

25 MR. DISKANT: That's correct, but so far it shouldn't

1 imply that the '444 is on its screen. There is no '444 patent
2 at issue in the Patent Office. This issue exists only in this
3 court.

4 So with that, let me begin.

5 Woops. Didn't work. There we go. Now it's working.

6 Okay. Let me just do a primer on obviousness-type
7 double patenting.

8 Why isn't it working? It's fallen asleep, I'm told.
9 I'm sorry.

11:36 10 THE COURT: I thought it was me.

11 MR. DISKANT: It's not working. I'll try again. Yes.
12 Okay.

13 So this is a quote from a pre-*Gilead* case. "The
14 judicially created doctrine of obviousness-type double
15 patenting prohibits a party from obtaining an extension of the
16 right to exclude through claims in a later patent that are not
17 patentably distinct from claims in a commonly owned earlier
18 patent." The words I want to emphasize there are "prohibits a
19 party from obtaining an extension of the right to exclude."
11:37 20 Because before *Gilead* and after *Gilead*, that is the idea.

21 And if you look, Your Honor, at the *Gilead* opinion
22 which you discussed with counsel earlier today, in the second
23 paragraph, the next to last sentence reads, "Because the
24 obviousness-type double patenting doctrine prohibits an
25 inventor from extending his right to exclude through claims in

1 a later-expiring patent, they're not patentably distinct from
2 the claims of the inventor's earlier-expiring patent."

3 We agree that the '375 patent is an obviousness-type
4 double patenting reference. Extending the right to exclude,
5 that's the idea; and when you get into the cases, it's
6 unjustifiably extending the right to exclude, and that's a
7 fundamental problem with the entire argument over there,
8 because you cannot craft a coherent sentence that says the '444
9 patent extended the '471 patent. It didn't extend it. The
11:38 10 '471 patent already existed. It expired later. It didn't --
11 the '444 patent didn't extend it, and it certainly didn't
12 unjustifiably extend it because the difference in term was set
13 by Congress.

14 THE COURT: But something that's come -- perhaps
15 you'll get to this. Something that's come into sharper focus
16 as a result of the defendant's argument is Congress legislates
17 presumably in the context of a known body of law. Part of that
18 law was, in 1995, obviousness double patenting.

19 MR. DISKANT: Right.

11:39 20 THE COURT: So I think the defendant is arguing
21 there's nothing in the legislation that manifests an intent to
22 alter that, and in *Gilead*, the Federal Circuit says that a
23 later-issued patent can be a reference for an earlier-issued
24 patent.

25 MR. DISKANT: That's correct, Your Honor. But the

1 key -- and I will show this as we go through it -- before
2 *Gilead* and after *Gilead*, the ultimate question is whether the
3 '444 patent in our case is extending the right to exclude. So
4 that's what Congress legislated against.

5 THE COURT: I think the defendants will say it would.

6 MR. DISKANT: They don't talk about -- I'm sorry.

7 THE COURT: Anyway. Go ahead. Go ahead.

8 MR. DISKANT: They don't talk about extending.

9 They're not going to utter a sentence that says the '444 patent
11:40 10 extends the term of the '471 patent. It doesn't. And so when
11 Congress legislates, yeah, that's what it legislated against,
12 and when Congress, not in the 1800s, but when it wrote the GATT
13 legislation, it has a special provision that talks about the
14 longer of two terms. And that's essentially extending the
15 term. Do we take the shorter term or longer term? The
16 extension that Congress granted is the longer term. So that is
17 the conflict.

18 THE COURT: And you had that until 2004, I think, when
19 the '444 was issued. If you had wanted, without any question
11:41 20 like this one, to have a term until 2018, you wouldn't have got
21 the '444.

22 MR. DISKANT: Well, that's true, but it's
23 linguistically -- it doesn't scan to say that the '444 extended
24 the term of the '471. And there's been argument about it and
25 Your Honor's been interested in why didn't we apply for the

1 '444. I've got to tell you there's nothing in the record on
2 this subject. If Your Honor thinks that matters, we're not
3 ready to talk about summary judgment. I personally don't think
4 it matters, but I should at least say that big companies like
5 Johnson & Johnson and like Pfizer have teams and teams of
6 patent lawyers who write patents on variants of their
7 inventions, and they're subject -- in this case, the '444 was
8 subject to policing by the Patent Office. It issued a double
9 patenting rejection of the '444 patent under existing law,
10 which is, it's going to be the later patent. If there's a
11 problem it's with the '444. You need a terminal disclaimer.
12 And we issued a terminal disclaimer. And in terms of taking
13 risks, the body of law that we're talking about didn't exist
14 until 2010 when we applied for the --

15 THE COURT: I'm sorry. What body of law is that?

16 MR. DISKANT: The body of law that is now the *Pfizer*
17 case, the two District Court cases from pre-*Gilead*, *Gilead*, all
18 these cases apply a different form of analysis. Prior to 2010
19 the only analysis in double patenting law was which patent
20 issued later. That was it. And so because the '471 issued
21 first, there was no issue. There was no risk being taken. It
22 was an after developed body of law. I understand bodies of law
23 can change, but it doesn't mean when we applied for the '444 we
24 were taking any sort of risk at all under existing doctrine.

25 Anyway, let me proceed, if I may. There are two

1 justifications for double patenting. One, unjustified
2 time-wise extension, unjustified extensions. The second is
3 multiple infringement suits by the same inventor. It's always
4 considered a secondary issue. I agree with that. It
5 doesn't -- it's not an issue in our case. But it's the other
6 reason that these things exist.

7 And if you care, I'll just give you an example of why
8 the issue exists. If you have two patents that are patentably
9 indistinct, I own them both, well, I can sue -- but what if I
11:44 10 sell one of them to my next-door neighbor? So now two
11 patentably indistinct patents are owned by two separate people
12 and there could be vexatious litigation. That's the other
13 reason for the doctrine. And the terminal disclaimer that we
14 signed takes that out of play. We agreed we would not separate
15 ownership.

16 So here we've got the issue in this case, which is how
17 to analyze these two justifications in double patenting
18 doctrine in light of this -- when the only difference in term
19 is the result of the change in the law and not something that
11:44 20 the patentee did to extend term. So here are the -- I'd like
21 to just talk for a moment about before and after the URAA.
22 Before the URAA, going back as Mr. Hurst says 100 years or
23 more, 17-year term from issue; that was the law.

24 So this illustration shows what double patenting was
25 concerned about. It was concerned about an applicant -- in

1 this illustration, patent B -- manipulating the issue date to
2 make the term longer, like this. I don't know if the image
3 that we printed shows the change. It may or may not. But this
4 is manipulation. You're in the Patent Office. You have two
5 patents, and you stall one of them, and you stall it so that it
6 issues later. And lo and behold, patent B has a longer term
7 than patent A even though they're indistinguishable. That's
8 double patenting. That's the problem that it's addressing, and
9 that's what the courts talk about, several sequential patents
11:46 10 on the same invention.

11 After the URAA, things changed because the issue date
12 didn't matter any longer for term. After the URAA what
13 mattered for patent term was the priority date. And the
14 priority date may be the date you file it, but it may relate
15 back to an even earlier patent. So now I'm illustrating two
16 patents, patent A and B, and in this example, patent B issued
17 first, so there would be, under preexisting law, no worries
18 about double patenting. But the *Gilead* court recognized that
19 there was a different kind of manipulation possible after the
11:46 20 URAA, and that was the priority date.

21 So now I'll illustrate here the later filing. And by
22 manipulating the priority date, you got 20 years at the other
23 end. Both of these illustrations show an improper extension of
24 term. That's the issue in double patenting, extending the term
25 beyond what it should be. That's what drives the

1 judicially-created doctrine.

2 THE COURT: But let's pause for a minute here.

3 MR. DISKANT: Sure.

4 THE COURT: This overlaps a bit with the reexamination
5 issue. But in your view, does the subjective intent or motive
6 for the conduct of the patentee make any difference?

7 MR. DISKANT: It doesn't under existing law. And the
8 reason is, basically, the law has essentially said this is a
9 situation that is subject to manipulation. That's good enough
11:47 10 for us. We're not going to be concerned whether you did or
11 didn't do it. So here, in this example, patent B is subject to
12 manipulation by adjusting the priority date, comparing it to
13 the other. That's what the issue is.

14 And the *Gilead* court talks about this risk of
15 manipulation, and, you know, what a patentee could do now post-
16 URAA by altering priority dates. Okay? So these are just the
17 two different examples, both illustrating extending the term
18 through something the patentee does. Winding up --

19 THE COURT: The record won't reflect that really neat
11:48 20 moving slide that you have. You have to give a disc to the
21 Federal Circuit.

22 MR. DISKANT: Okay. We'll get you a disc.

23 THE COURT: I don't need it.

24 MR. DISKANT: I'm teasing. It's just an illustration.
25 I can draw it without --

1 THE COURT: It's very nice. Good advocacy.

2 MR. DISKANT: Anyway, now we want to look at these two
3 patents, the patents-in-suit. So now we're talking not about a
4 statute from 1860. We're talking about the URAA, which
5 Congress recognized that there would be patents that
6 overlapped. You know, patent gap kind of filling patents.

7 So the law chose to give patents like the '471 the
8 greater of the 20-year term or 17 years from grant, and that's
9 the law. That's a choice. Now, in making that choice, you
11:49 10 know, Congress certainly recognized that there would be patent
11 families like ours in which some patents were filed before and
12 some patents were filed after and is essentially saying, If you
13 file after, you're going to get 20 years from the priority
14 date. If you file before, you may have a different term. Even
15 though the essential point of GATT or URAA was to have all
16 these patents have the same term related to the priority date,
17 Congress is going to allow some patents to extend further, our
18 patent.

19 THE COURT: Well, a couple of things. What you argue,
11:50 20 that Congress knew that there would be -- you know, that there
21 often were and continue to be families of patents and some
22 related patents would be issued before 1995 and other related
23 patents after, and the calculation of their expiration date
24 would be different.

25 MR. DISKANT: Yes.

1 THE COURT: I don't think anybody's, to my knowledge,
2 cited to me any legislative history about that.

3 MR. DISKANT: That's correct. There is nothing that
4 says that. I'm just saying that this is so widely known in the
5 world that I'm assuming Congress must have --

6 THE COURT: And it seems to me the other side of the
7 coin from the argument the defendant was making, that Congress
8 also knew about this doctrine of obviousness double patenting.

9 11:51 10 MR. DISKANT: Completely correct, but that's about
unjustifiably extending the term. Congress is by law extending
11 the term. That's the difference.

12 THE COURT: Well, I mean, this is something I've been
13 wrestling with. This has particularly engaged my interest. It
14 may be that the '444 had the practical effect of extending the
15 term of the '471, because the '471 evidently was vulnerable to
16 being found -- this is why I'm saying it -- you're shaking your
17 head -- so you can address it -- vulnerable to being found
18 invalid in view of maybe the two patents involved in a
19 reexamination issue that we'll get to or for some other reason.
20 And maybe in the absence of the '444, somebody would have
21 developed an invention that arguably infringed the '471 with
22 some confidence that it could demonstrate the '471 was invalid
23 but were deterred from doing that by the existence of the '444.

24 MR. DISKANT: Judge, I hate to say this. This is the
25 wildest of speculation. There is nothing in the record. I'll

1 give you some objective facts that are true. What's true is
2 these are both patents on a biological product. It's true that
3 a biological version of Remicade could not be launched under
4 the BPCIA until after 2010. It's true that these folks are out
5 there still not having launched a biological version of the
6 BPCIA. I can't tell you why the '444 was applied for, but this
7 is just utterly routine in the patent prosecution business.
8 And let me just say, it's completely baseless to speculate that
9 someone thought there was some validity problem with the '471.
11:53 10 I don't know why they wanted this. It expired in 2011. There
11 was not a chance on the face of the Earth that there was going
12 to be a competitor of Remicade before 2011. They didn't -- but
13 I don't think we can --

14 THE COURT: Boy, if you've got a patent that's
15 generating billions of dollars of year and you've got a
16 doctrine of obviousness double patenting, why would you
17 jeopardize that by getting a second patent for something that
18 you already have a patent of?

19 MR. DISKANT: Because the doctrine --

11:54 20 THE COURT: Just because some scientist is sitting
21 there or some person is sitting there writing patents?

22 MR. DISKANT: That is in fact what happens, but that's
23 outside the record, too.

24 THE COURT: They may sit there and write patents, but
25 I doubt -- I suspect somebody's looking at this pretty

1 carefully and saying what are the implications going to be for
2 the patents we already have?

3 MR. DISKANT: With all respect, Judge, it is
4 inconceivable that anybody worried about double patenting with
5 respect to these two patents.

6 THE COURT: I'm so impressed by you and your
7 colleagues. It seems to me inconceivable that this all
8 happened by accident.

9 MR. DISKANT: Well, I'm not prepared to make up
10 reasons. This is just what happened. And again, if Your Honor
11 thinks this is actually important, we need discovery on it. I
12 don't think it matters, but I don't think that it's a
13 reasonable speculation that double patenting concerns about the
14 '471 had anything to do with this. The '471 was a 17-year
15 patent. This was just a little, you know, small patent that
16 was during its term.

17 THE COURT: The '471 covers a genus, right, a group of
18 antibodies?

19 MR. DISKANT: Yes, yes.

11:55 20 THE COURT: And the '444 is for a specific antibody
21 that's part of that group.

22 MR. DISKANT: I think that's not correct, but I'm not
23 sure. I'm getting -- I know that's true in the other part of
24 the case, in the '195 and the '272. No. This is very similar.
25 It includes both. I think it includes both.

1 THE COURT: I'm right, correct?

2 MR. DISKANT: You're right, in part. That is to say
3 it includes a species and it also includes the genus.

4 THE COURT: Okay. So the genus is the '471, correct?

5 MR. DISKANT: Yes.

6 THE COURT: A genus is a group?

7 MR. DISKANT: Yes.

8 THE COURT: It's a group of antibodies?

9 MR. DISKANT: Yes.

11:56 10 THE COURT: And one of the antibodies is --

11 MR. DISKANT: CA2.

12 THE COURT: That's easier to say then --

13 MR. DISKANT: Infliximab. Definitely easier.

14 THE COURT: Okay. But it includes infliximab,
15 correct?

16 MR. DISKANT: Mm-hmm.

17 THE COURT: Then the '444 is a patent that's specific
18 to infliximab?

19 MR. DISKANT: It has a claim that is specific to
11:56 20 infliximab, and it has another claim that's the same genus
21 claim as the -- frankly, if it just had species claims, we
22 would be having a different argument.

23 THE COURT: All right.

24 MR. DISKANT: It doesn't matter.

25 THE COURT: But it's patentably indistinct?

1 MR. DISKANT: They're patentably indistinct because
2 they both have the genus claims. I don't think any of this
3 matters for this purpose.

4 THE COURT: That's okay.

5 MR. DISKANT: But I urge you strongly to resist the
6 urge to speculate that some double patenting concern was behind
7 the '444 patent. I just don't see a record basis for that.

8 THE COURT: Well, is it in the record that the PTO has
9 found the '471 invalid in view of patents other than the '444?

11:57 10 MR. DISKANT: It should be.

11 THE COURT: Is it -- it's the next motion.

12 MR. DISKANT: It's in the record in the other motion.

13 THE COURT: Right. So I don't know why it would be
14 wildly speculative. It's occurred. Look at all these lawyers.
15 One of you would have seen it. Anyway. Go ahead.

16 MR. DISKANT: I'll say at the highest level, the
17 reasons to file multiple patents that are similar to one
18 another, the highest level are to protect against validity
19 risks and infringement risks. I agree with that. I'm just
11:58 20 reacting to what sounds like an unwarranted, very specific
21 speculation about what's going on here. I don't know what's
22 going on here.

23 But let me just pause to talk about these two patents
24 before the URAA and after the URAA because there would be no
25 double patenting issue for either one under either regimen.

1 Now we're looking at a slide that says if neither patent was
2 subject to the URAA, if that was the case, the '471 patent
3 would issue in 2018.

4 THE COURT: Sorry. Which number?

5 MR. DISKANT: This is now number 18. If that were the
6 case, the '471 patent would issue 17 years later in 2018 and
7 the '444 patent would issue 17 years later in 2021. So that's
8 if the URAA didn't apply.

9 THE COURT: The URAA didn't exist.

11:59 10 MR. DISKANT: That's right. I'm just setting up the
11 markers.

12 THE COURT: If it didn't exist?

13 MR. DISKANT: Right, if it didn't exist, that's fine.

14 THE COURT: The old system.

15 MR. DISKANT: The old system. I'm just trying to
16 explain that under the old system, the issue would be with
17 respect to the '444 patent, which expires later under the old
18 system. And so that PTO would enforce that as a terminal
19 disclaimer, which is exactly what it did. So under the old
12:00 20 system, both patents would expire in 2018. And we filed for
21 the '444 a couple of years earlier.

22 Now, under the new system, the URAA system, both
23 patents would expire on the same date, 20 years after the
24 priority date. So I guess what I'm saying is under the old
25 system, there would be no double patenting issue. And if both

1 patents were both under the new system, there would be no
2 double patenting issue. And the dispute therefore is not the
3 result of double patenting issues. This dispute that we're
4 having is solely the result of two different terms that were
5 set by Congress, one for the '444 and one for the '471. And
6 likewise, there would be no conceivable manipulation under
7 either pre- or post-URAA law. We did not cause the '471 patent
8 to issue later. It issued earlier. And we didn't cause the
9 '471 patent to have a later priority date. It has the same
10 priority date. So both of the concerns are actually identified
11 in the case law. Shifting the issue date to get an extension,
12 we didn't do that. Shifting the priority date to get an
13 extension, we didn't do that either. It's just a matter of the
14 change in the law. So now -- do you have a question?

15 THE COURT: No.

16 MR. DISKANT: Okay. Sorry. I wasn't sure.

17 THE COURT: Well, okay. Now I do have a question.

18 MR. DISKANT: Yeah.

19 THE COURT: But this may not be -- does the statute
20 expressly address what happens in view of double patenting law
21 in a situation like this where one patent was applied for
22 before 1995 and another patent was applied for after 1995?

23 MR. DISKANT: No, which is why we have an issue. I
24 would say, although the statute is silent on it, by expressly
25 articulating a longer term Congress is justifying a longer

1 term. Contrary --

2 THE COURT: But in terms of -- I think I understand
3 that argument, but I just want to kind of go step by step to
4 get there. So the statute doesn't address the factual scenario
5 in this case?

6 MR. DISKANT: Correct.

7 THE COURT: I view my task as essentially doing two
8 things. One, determining what Congress would have done if it
9 had addressed this issue; and then two, predicting what the
12:03 10 Federal Circuit will say Congress would have done if it
11 addressed this issue. To me, that's the proper framework for
12 analysis.

13 MR. DISKANT: That's a perfectly reasonable framework.
14 My only quibble would be you would have the legal question --
15 well, that's fine. I think that's fine.

16 Okay. So *Gilead*, we're now looking at the *Gilead*
17 issue. Under pre-URAA law -- this is now slide 24 -- there was
18 no double patenting issue because the '483 patent had issued
19 first. That's what *Gilead* argued. But the *Gilead* court
12:04 20 identified a problem that is a real problem that exists
21 post-URAA and not before, which I'm illustrating here on slide
22 25, which is the manipulation of priority date.

23 So essentially, these two patents, which were
24 patentably indistinct, had different priority dates. And as a
25 result, the patentee could fairly be said to have extended the

1 term of the '483 patent by its actions. It filed first the
2 priority application for the '375 and then later it did
3 something else, extended the term of that patent by filing the
4 later priority application for the '483. I think that's why
5 *Gilead* and the pre-*Gilead* law all talk about something that the
6 patentee did to extend the term of a patent, not something it
7 did as we did that they're arguing shortened the term of the
8 patent.

9 THE COURT: In *Gilead* the District Court found there
12:05 10 was no gamesmanship.

11 MR. DISKANT: Yes.

12 THE COURT: Even though the effect was to extend the
13 term of the patent.

14 MR. DISKANT: Yeah, mm-hmm.

15 THE COURT: And the Federal Circuit said it's not
16 relevant whether there was gamesmanship or not.

17 MR. DISKANT: Yes and no. I think the Federal Circuit
18 was extremely interested in the potential for gamesmanship. So
19 just as I said to you earlier, it doesn't matter why one patent
12:05 20 issued first. It's the potential for gamesmanship that is the
21 heart of this inquiry, and we don't have to second-guess --

22 THE COURT: But I don't know that the potential for
23 gamesmanship is the heart of the inquiry. In *Gilead* the
24 Federal Circuit says repeatedly having stable dates for the
25 expiration of patent protection --

1 MR. DISKANT: Yeah.

2 THE COURT: -- and I think -- we can go up. The
3 primary ill to be protected against is preventing the public
4 from practicing an invention when one patent on that invention
5 has expired. So that to me, at the moment, seems to be the
6 thrust, the dominant principle of *Gilead*.

7 MR. DISKANT: I understand why Your Honor may be
8 reading it that way. I think that's not in the end the heart
9 of the matter, which I'd like to explain to you. I think the
12:06 10 heart of the matter is the paragraph I just read you from the
11 second paragraph of *Gilead*, about "prohibits an inventor from
12 extending his right to exclude." If there's nothing you can
13 point to that the inventor did to extend his term, then
14 *Gilead*'s not really interested. And we will talk quite
15 extensively -- I will in a moment -- about the freedom of the
16 inventor of the public. I'll get there in a few minutes. But
17 the core rejoinder to that or understanding of that is that is
18 a generality and no more than a generality with numerous
19 exceptions, and therefore it simply sets up the question Your
12:07 20 Honor is to decide, it doesn't decide the question.

21 THE COURT: Hold on just one second.

22 MR. DISKANT: Sure.

23 THE COURT: Go ahead.

24 MR. DISKANT: Okay. So in any event, these are the
25 facts of *Gilead*. The priority date was extended, extending the

1 term of the second patent. And the court said, If we were to
2 hold that the issue date is the determining factor, it would
3 make this subject to significant gamesmanship. And it repeated
4 that. Again, I don't need to read them all to you. But such
5 significant vacillations in an inventor's period of exclusivity
6 is prone to gamesmanship. So gamesmanship certainly runs
7 through *Gilead* as a significant part of the concern about
8 moving priority dates.

9 THE COURT: Is that the only form of possible
12:09 10 gamesmanship?

11 MR. DISKANT: Frankly, that's the only line to
12 actually think of -- maybe there are some others. I don't
13 know. Putting it differently, on the one hand the courts say
14 however you do it. On the other hand, the only two examples
15 I've ever seen in any case are post-*Gilead*, sliding the
16 priority date, and pre-*Gilead*, sliding the issue date. Those
17 are the only ways I've seen -- I'm sorry.

18 THE COURT: I'm just thinking out loud. Does a form
19 of gamesmanship -- the '471 exists, it would expire if it stood
12:09 20 alone in 2018. There's a perception that it may be vulnerable
21 for being held invalid. So a narrower patent, the '444, is
22 obtained. So now you have one patent that expires in 2018 if
23 it's valid and another patent that has a stronger case for
24 validity that expires earlier. But for at least that period to
25 2011 it gives you protection and then it lets you argue that

1 you should have that protection until 2018. Is that
2 gamesmanship?

3 MR. DISKANT: Two answers. First -- well, three
4 answers. First, we're just making up that one has a stronger
5 argument than the other. I have no idea. Just arguendo, I
6 agree that the reason you apply for patents is to have more
7 defenses. I agree with that.

8 THE COURT: To have more defenses?

9 MR. DISKANT: Yeah, but that is not gamesmanship.

12:11 10 That is what the Patent Office allows you to do. The
11 gamesmanship that is relevant, the only germane gamesmanship to
12 double patenting is improper extensions of term. It's not
13 having multiple patents on the same subject that can be
14 attacked through different doctrines or not. But that is not
15 double patenting. Double patenting is only about unjustified
16 extensions of term. And if you can't say how the '471
17 patent -- excuse me -- if you can't say how the '444 patent
18 extended the term of the '471 --

19 THE COURT: No, it didn't. If I'm persuaded by the
12:11 20 defendants, it will have reduced the term.

21 MR. DISKANT: Right. That's exactly right. That's
22 exactly their argument. Their argument is that there's a
23 double patenting violation because the '444 patent reduced the
24 term of the '471. That's it. That's got nothing to do with
25 double patenting. That's, in the end, the point.

1 THE COURT: Well, it does have to do with -- whatever
2 the purpose is, the Federal Circuit said that a later-issued
3 patent can be the reference for an earlier-issued patent, and
4 if obviousness double patenting exists, the second, the
5 first-issued patent is invalid. That's the general holding.
6 They may have had -- the language is much broader than
7 gamesmanship. And then *AbbVie* -- if I'm saying it right --
8 *AbbVie* confirms the durability of the doctrine of double
9 patenting.

12:12 10 MR. DISKANT: I agree with all of that. But I don't
11 agree that the doctrine has nothing to do with improper
12 extension of term.

13 THE COURT: I didn't say it had nothing to do with it.

14 MR. DISKANT: Well, that's all that the Federal
15 Circuit has ever upheld as a reason for double patenting
16 invalidity: Improper extension of term. And in *Gilead*, they
17 recognized that issue date wasn't determinative because you
18 could improperly extend the term by manipulating the priority
19 date. And so that's what they did.

12:13 20 Now, Celltrion has two arguments: First, that *Gilead*
21 has decided it, and secondly, that *Gilead*'s principles decide
22 it. Your Honor has said you were not inclined to believe
23 *Gilead* decided it.

24 THE COURT: Correct.

25 MR. DISKANT: I'll go through that pretty quickly, but

1 I just want to make a couple of points.

2 THE COURT: Okay.

3 MR. DISKANT: First, the circumstances of this case
4 are referred to both at the beginning and the end of the
5 decision. I'm now up to slide 32.

6 THE COURT: 32?

7 MR. DISKANT: Yeah. And I heard counsel's argument
8 the circumstances of this case are two URAA patents, and I
9 don't actually think that's subject to serious disagreement
12:14 10 notwithstanding the argument I just heard. And they repeat the
11 circumstances of the case again at the end of the decision. So
12 they've written -- you know, when courts say that, they're
13 intentionally singling something out.

14 THE COURT: Well, essentially what it communicates --
15 I sit under portraits of Louis Brandeis in my office, which is
16 a humbling experience. But, you know, you don't decide, at
17 least on constitutional issues, you don't decide more than is
18 necessary to resolve the case.

19 So the *Pfizer* footnote tells me they were aware,
12:14 20 foresaw the factual scenario of this case, and they told us
21 about it, us district judges. Then, you know, the language
22 here I think can fairly be read to say what you're saying,
23 under the circumstances of this case. So in my view at the
24 moment, Congress hasn't decided the issue. The Federal Circuit
25 hasn't decided the issue. But I have a duty to decide the

1 first instance how I think Congress would have decided the
2 issue if it had addressed it and to take guidance from *Gilead*
3 in answering that question.

4 MR. DISKANT: I think that's correct. But at the same
5 time, while it's true the courts should only decide the
6 question in front of them, we all know, because we've read so
7 many decisions that aren't so carefully written, and this is a
8 carefully written decision, obviously, it's carefully written
9 to signal what it's not deciding as well as what it is
10 deciding.

11 THE COURT: So I think this issue that I have to
12 decide is not decided by *Gilead*. It's not a precedent that I
13 have to follow because there's a factual difference. There's a
14 factual distinction that may make a difference in the outcome.
15 But what about footnote 2 and the reference to *Pfizer*? It
16 appears to me that they're signaling that the Patent Appeals
17 Board properly decided *Pfizer*.

18 MR. DISKANT: I don't read it that way, although I can
19 understand why you might choose to disagree. But the way I
20 read it is the District Court in *Gilead* had relied on the two
21 District Court cases that actually decided our issue our way.
22 And so the Federal Circuit was saying, Well, that's not
23 actually the issue here. And then it cites *Pfizer*. And I
24 don't know why you know why the District Court didn't cite --
25 it's not like *Pfizer* was a secret because *Pfizer* is actually

1 expressly addressed in the two District Court cases, said that
2 that District Court relied on it.

3 But why is the Federal Circuit citing *Pfizer*? My view
4 is to say, A, there's a disagreement; and B, the principle of
5 the *Pfizer* court is the one they are bound to rely upon for
6 their decision.

7 THE COURT: Who is?

8 MR. DISKANT: The Federal Circuit.

9 THE COURT: The Federal Circuit is bound by something
12:17 10 the Patent Office decides?

11 MR. DISKANT: No, it's not. What I'm saying is that
12 the *Pfizer* PTAB decision, the Board of Appeals decision, said
13 language about the right, freedom to practice a patent, and the
14 Federal Circuit was about to say similar things, so it
15 liked it. I don't view it as more than signaling there's a
16 dispute and that it's not deciding this issue, which I think is
17 the most important thing.

18 So let me -- obviously you've seen all the different
19 references to URAA. Let me signal one that is particularly
12:18 20 important to me. It's right here. It's on slide 38.

21 THE COURT: What page of *Gilead*?

22 MR. DISKANT: Oh, from *Gilead*. It's 1216.

23 THE COURT: Let me just take a break.

24 MR. DISKANT: Sure.

25 THE COURT: Go ahead.

1 MR. DISKANT: Permitting -- and they don't come out
2 anywhere and really expressly say a holding other than who
3 wins. But I think this is as close as they come to a holding.
4 "Permitting any earlier-expiring patent to serve as a double
5 patenting reference," so okay, that's the '444 patent.

6 THE COURT: Hold on just a second. This is page 1216?

7 MR. DISKANT: Yeah. It's headnote 7 in my copy. I
8 don't know if that's where you are. It's four paragraphs above
9 IV.

12:20 10 THE COURT: I'm not finding it.

11 MR. DISKANT: Let's see. If you go to -- did I give
12 you the right page? 1216. 1216 begins "now" in the same
13 paragraph --

14 THE COURT: "Now if the '375"?

15 MR. DISKANT: Yeah, two paragraphs down, "looking
16 instead."

17 THE COURT: "Looking instead," okay.

18 MR. DISKANT: Then the last sentence in that
19 paragraph?

12:20 20 THE COURT: "Permitting."

21 MR. DISKANT: Yes, yes. That's where it is.

22 "Permitting any earlier-expiring patent to serve as a double
23 patenting reference." Okay? The '444 patent is an
24 earlier-expiring patent. For a patent subject to the URAA,
25 that is, for a patent in which the priority date is the

1 determinant of the expiration date. The '471 patent is not a
2 patent subject to the URAA. It's a pre-URAA patent. So that's
3 what it's saying. It says, "Permitting the '444 patent to
4 serve as a double patenting reference for URAA patents is
5 okay." That's stable. That preserves the public's right to
6 use the invention.

7 THE COURT: But here. Let me think along with you.

8 MR. DISKANT: Sure.

9 THE COURT: Because I underlined this, too. But I
10 understand the '471 is a pre-URAA patent. Let's leave that
11 out.

12 "Permitting an earlier-expiring patent," '444, "to
13 serve as a double patenting reference guarantees a stable
14 benchmark that preserves the public's right to use the
15 invention and its obvious variants that are claimed in a patent
16 when that patent expires."

17 See, this is something -- it's an open issue, I had
18 left out the pre-URAA because that's a factual distinction.
19 But here, the Federal Circuit is communicating to me that
20 preserving the public's right to use the invention and its
21 obvious variants is an important purpose and that the
22 plaintiff, having decided to get two patents, the Federal
23 Circuit is I think at the moment likely to give priority to the
24 public's right to practice the invention over the inventor's
25 right to have a monopoly for an extended period of time because

1 it risked that monopoly when it got the second patent.

2 MR. DISKANT: I think that that doesn't grapple with
3 the core proposition of double patenting going back to the
4 1800s, which is improperly extending the term. So there are
5 many circumstances where a term may be extended properly. And
6 the *Gilead* court, we'll see in a moment, recognizes that.

7 Let me skip ahead and show you one. For example,
8 slide 46, this is the one that comes probably closest of them
9 all. This is note 6 in *Gilead*.

12:23 10 THE COURT: Note 6?

11 MR. DISKANT: Yeah.

12 So this drafts from a sentence that says -- it's
13 talking about expiration dates versus issue dates. And it
14 says, "There are exceptions to that rule, of course, such as
15 patents that qualify for term extensions, but none are relevant
16 to the facts of our discussion here."

17 So let me tell you what a term extension is. Congress
18 decided that sometimes the FDA takes too long to approve a
19 drug, and the patent clock is ticking, and the patent owner may
12:24 20 wind up, you know, not getting any protection from his patent.
21 So Congress permits the FDA to allow the extension of one
22 patent. The patent owner decides what it is. And essentially
23 what that means is, if that were our case here -- well, let's
24 not make it our case. It's too complicated. Well, I can deal
25 with it, but it's something that became more complicated than I

1 wanted to make it.

2 If you have two patents that expire on the same day,
3 post-URAA, they have the same priority date, Congress allows
4 one of those to be extended. And the Federal Circuit is
5 clearly saying, We're not saying there's anything wrong with
6 that. We're not saying that extending it one term, even though
7 there's a previously expiring, indistinguishable patent is
8 going to present a problem. And the reason for that is that's
9 a justified extension of term.

12:26 10 Now, in our case, we don't have an extension of term.
11 We have a shortening of term. And the term of the '471 is
12 justified, it's set by Congress. So I think when you get down
13 to the complicated smaller issues besides the
14 patents-want-to-be-free kind of argument or
15 inventions-want-to-be-free kind of argument, there's a lot of
16 complexity here, and you have to have an unjustified extension
17 of term before the Federal Circuit, before or after *Gilead*, is
18 going to invalidate a patent for double patenting.

19 THE COURT: That footnote is to the sentence that
20 says, "As discussed above, the primary ill avoided by
21 enforcement of the double patent doctrine is restriction on the
22 public's freedom to use the invention claimed in a patent and
23 all obvious modifications of it after that patent expired." At
24 least that's in the same paragraph.

25 MR. DISKANT: Yeah, that's right.

1 THE COURT: So this so far has communicated -- I mean,
2 this contributes to my tentative view, which you're
3 challenging, that the Federal Circuit would fill in -- you
4 know, say Congress would fill in the statutory gap by saying
5 that Janssen had 17 years to 2018 for the '471 patent and then
6 it made a choice and got the '444, with the 2011 expiration
7 date. And using the 2011 date would avoid the primary ill of
8 giving patent protection beyond 2011 when one of the two
9 patents it chose to get expired. So how do you respond to
12:28 10 that?

11 MR. DISKANT: I think it says just exactly the
12 opposite, so let me try.

13 THE COURT: I hope it's really not laughable.

14 MR. DISKANT: I'm sorry. I've spent far too much time
15 with this.

16 THE COURT: Well, go ahead.

17 MR. DISKANT: I apologize. It's not laughable. But
18 it does say exactly the opposite to me. And the reason it says
19 exactly the opposite to me is it's saying by and large the
12:28 20 public should have the right to practice a patent after it has
21 expired, but there are exceptions to that. And the exception
22 would be -- so in this hypothetical, you have two patents that
23 expire on the same date and they're patentably
24 indistinguishable. And maybe there had been a terminal
25 disclaimer. These are two patents that are indistinguishable

1 and have expired, but FDA is permitted by Congress to extend
2 one of the two terms. And the footnote is saying to me that
3 that's different, that it's okay if the FDA permits an
4 extension of one of two patents and that may hamper the
5 public's ability to practice the one that's expired, but that's
6 permitted by statute, Congress has approved that, that's all
7 right. That's how I would read that.

8 THE COURT: Then your argument is Congress has said
9 it's also our right to have 17 years on the '471?

12:30 10 MR. DISKANT: Correct. Rather than 20 years from the
11 priority date. That's exactly right, Judge. And I do
12 apologize. I have spent way too much time with this.

13 THE COURT: Well, there's a lot riding on it.

14 MR. DISKANT: So let me just go back where I was. I'm
15 now back on 38, so I think the this language is quite advertent
16 and you can't ellipsize out the four patents subject to the
17 URAA, that the stable benchmark comes in this post-URAA world.
18 In the pre-URAA world, the issue date was what mattered.
19 That's what people --

12:30 20 THE COURT: I get that. I understand that.

21 MR. DISKANT: Okay. In any event, *AbbVie*, same facts.
22 I'm just showing you the illustration of the priority date
23 shift in *AbbVie*. Same facts. Okay.

24 THE COURT: Same facts as what?

25 MR. DISKANT: As *Gilead*, sir. The '444 priority

1 application shifts the extension so you can fairly and
2 accurately say that the patent date unjustifiably extended the
3 term of the '442 patent by giving it a later priority date.
4 Squarely within the norm of double patenting case law, okay?
5 How do we think about these two patents, the '444 and '471?
6 First they say *Gilead* decides the issue. It doesn't. So here
7 is the issue. And I've put on slide 42 what I think the
8 conflict is.

9 The conflict is between the principle the public
10 should be free to practice a patent after its term has expired
11 and the statute in which Congress gave the pre-UAAA patents the
12 greater of 17 or 20 years. And in the end, that's the entirety
13 of this dispute, because there is no argument that the priority
14 date was manipulated, and there's no argument that the issue
15 date was manipulated. The only question is the effect, the
16 impact of the change in the law. So *Gilead*'s bedrock
17 principle, the public is free to use a patent after it expires.
18 And that is certain a principle of law. But *Gilead*, to my
19 reading, somewhat overstates that principle because there are
20 many exceptions to it as well.

21 And here is a quote from another Federal Circuit case.
22 "The patent does not provide the patentee" --

23 THE COURT: Which slide is this?

24 MR. DISKANT: I'm sorry. That's slide 45.

25 The patent does not give you the right to do anything.

1 Its expiration doesn't give you the right to do anything.
2 There may be other patents that interfere. So a frequent
3 example is, you know, the black and white TV and the color TV
4 and you have a patent on both, and the black and white patent
5 expires. Well, you still can't make a color TV because there's
6 still another patent in the way. And so the Federal Circuit
7 acknowledges that this is a general principle that doesn't
8 always apply. And on slide 46, we have the point we were just
9 talking about, that where there's a patent term extension, one
10 patent may expire and the other patent may be extended, and the
11 public isn't free. The public is still bound by the extended
12 patent. It's justifiably extended by Congress.

13 There's another note in *Gilead*. This is footnote 5 of
14 *Gilead*. It's on slide 47. "The public's ability to practice
15 an invention may be further restricted by an improvement
16 patent." That was the color TV and black and white example I
17 just gave you. So I would say that while, as a generality, the
18 public should be free to practice a patent after it has
19 expired, is a generality with many exceptions and we should
20 consider how it applies here.

21 THE COURT: Hold on for just a second.

22 MR. DISKANT: Sure.

23 THE COURT: Thank you. Go ahead.

24 MR. DISKANT: So the conflict is this other principle
25 of law, the statute. And Your Honor knows of course Congress

1 writes against a backdrop of the law, but the law as of the
2 date of this statute was that double patenting has no
3 application to later-issued patents.

4 THE COURT: Sorry. Say that again.

5 MR. DISKANT: That you can't use a later-issued patent
6 to invalidate an earlier-issued patent.

7 THE COURT: That was the state of the law in 1994?

8 MR. DISKANT: '95, yeah. All of these cases, all of
9 the double patenting cases --

12:35 10 THE COURT: What case stands for that proposition?

11 MR. DISKANT: I would say every double patenting case
12 we looked at.

13 THE COURT: So in 1994 and 1995, Federal Circuit --

14 MR. DISKANT: Slide 3.

15 THE COURT: Slide 3?

16 MR. DISKANT: That's just exemplary. But the *Gilead*
17 court says this --

18 THE COURT: Where?

19 MR. DISKANT: I'm sorry?

12:36 20 THE COURT: Where?

21 MR. DISKANT: The *Gilead* court repeatedly says -- so
22 I'm looking at page -- well, it's between footnote 5 and
23 footnote 6. *Gilead*'s response in that paragraph, *Gilead*'s
24 response is simply that the '375 we should focus on -- excuse
25 me -- that the '483 patent issued first. "We see little import

1 of that fact here. *Gilead* cites cases that describe the double
2 patenting bar as applicable to the second or later-issuing
3 patent." I would say those are each and every Federal Circuit
4 case on this subject prior to *Gilead*. And then *Gilead* says,
5 "but those cases dealt with patents to which the URAA did not
6 apply." So the law against which the -- and that's -- for
7 example, can I go to slide 3?

8 THE COURT: Actually, you may not have read all that
9 is helpful. It says, "But those cases dealt with patents to
12:37 10 which the URAA did not apply, and critical to a double
11 patenting analysis to patents for which the expiration date was
12 inextricably intertwined with the issuance."

13 MR. DISKANT: That's true. But that's an argument, a
14 gloss in those cases added by the *Gilead* court. The cases,
15 double patenting analysis, if you look at slide 3, is just an
16 example, "The judicially created doctrine of obviousness-type
17 double patenting prohibits a party from obtaining an extension
18 of the right to exclude claims in a later patent." Every
19 single case is about later patents.

12:38 20 THE COURT: Hold on just a second.

21 MR. DISKANT: Sure.

22 THE COURT: Interesting. When I hear briefly from the
23 defendants, I'd like them to address this issue particularly,
24 but go ahead.

25 MR. DISKANT: Sure. So if we go to slide 48 again and

1 look at Congress's statute. First they said, we, a pre-URAA
2 patent, is entitled to the greater of 20 years or 17 years from
3 the priority date, the greater. And then you want to know
4 what's Congress legislating against? I would say against two
5 principles. First, double patenting does not apply to the
6 first of two issued patents, and secondly, that, you know,
7 these shorter -- these post-URAA patents are going to be later
8 ones. They're not going to matter. They're going to come out
9 afterwards. And so, you know, there's nothing in this statute
12:40 10 that suggests anything other than that Congress intended a
11 patent such as ours to get 17 years from its issue date.
12 Again, as I said earlier, these patent families are
13 commonplace.

14 THE COURT: Why shouldn't I infer from the gap in the
15 legislation and the fact that Congress didn't address this that
16 they left it to the courts, primarily the Federal Circuit, to
17 decide how double patenting law -- which is a judicial
18 doctrine, right, not statutory double patenting?

19 MR. DISKANT: Yeah.

12:40 20 THE COURT: -- how double patenting law would operate
21 in a post-GATT regime.

22 MR. DISKANT: I think that's perfectly fair. I think
23 you can infer that, or you can decide Congress -- I think those
24 two modes of analysis essentially wind up in similar places.
25 But, yeah, it is a judicially-created doctrine, and Congress

1 was silent on it. However, it seems to me that one of the key
2 ideas of *Gilead* -- and this is on 1216 -- it's a simple idea.
3 "Congress could not have intended to inject the potential to
4 disturb the consistent application of the doctrine of double
5 patenting by passing the URAA." And I agree with that.

6 THE COURT: Where is this?

7 MR. DISKANT: It's on -- let me find it. It's the
8 paragraph that -- it's on 1610, I think. Excuse me. 1216. I
9 misspoke. The second paragraph from the top, second sentence.

12:42 10 THE COURT: Where do you think this is on 1216? Here,
11 I have it.

12 MR. DISKANT: You have it? "Congress could not have
13 intended to inject the potential to disturb the consistent
14 application." Now, to me --

15 THE COURT: Doesn't that support the defendant?

16 MR. DISKANT: I think not. I think the consistent
17 application is one has to look for unjustified extension of
18 term. And if you don't see unjustified extension of term,
19 there's no double patenting issue. And pre-URAA there was
12:42 20 unjustified extension of term related to issue dates.

21 Post-URAA there was unjustified extension of term based on
22 priority dates. But there has to be -- you have to be able to
23 say that the '444 patent extended the term of the '471 before
24 you enter the world of double patenting, and it did not do
25 that.

1 So for me, the question is resolving these two
2 conflicting principles, and I would say the first principle is
3 a generality, that is, the right to be free to practice patents
4 that sometimes applies and sometimes doesn't apply, whereas the
5 statute is quite specific. I would say I would resolve them by
6 finding in favor of the statute. Because here is what -- the
7 effect of Celltrion's argument is that -- I'm showing here the
8 timeline of the two patents. This is now on slide 52. And
9 essentially they're saying that the only way to preserve the
10 validity of the '471 patent, although it had already issued,
11 was to shorten its term. And again, to me that just doesn't
12 scan as a sentence. The '444 patent can't have extended the
13 term of the '471. They're saying it shortened the term.

14 Now, here I think is where the *Gilead* court lays out
15 the real principle. I'd like you to take a look at note 5,
16 please.

17 THE COURT: Note 5?

18 MR. DISKANT: Note 5. We looked at the first two
19 sentences, but I want to go to the last idea there. Because
20 after acknowledging that the public's right to be free to
21 practice an expired patent really is just a generality and is
22 not absolute, I think they say what the point of the whole
23 thing actually is in this footnote. The point of double
24 patenting doctrine is to protect the public from attempts by
25 inventors to effectively extend their patent term. So, you

1 know, that's their holding at the beginning, that the *Gilead*
2 plaintiffs have been properly extended their patent term.
3 That's the point of the analysis.

4 THE COURT: But I think the defendants would argue
5 that this in effect improperly or this in effect extends the
6 term of the '444 because they're overlapping patents.

7 MR. DISKANT: There's no way, I don't think, to craft
8 a sentence that says the '444 patent has extended the term of
9 the '471.

12:46 10 THE COURT: No. That the '471 has the practical
11 effect if your argument is adopted of extending the life of the
12 '444.

13 MR. DISKANT: How did the -- what attempt by the
14 inventor was there to extend the term of the '471 patent?
15 That's what the point of the doctrine is about. The inventor
16 did nothing to extend the term of the '471 patent. That would
17 be how I would read this, and I think that's the right way to
18 analyze this doctrine. These are the doctrinal underpinnings.
19 We go back to the doctrinal underpinnings of double patenting.
20 And they're not whether you got a patent because you were
21 worried about an infringement case. And it's not because you
22 got a patent because you were worried about an obviousness case
23 one day. It is two things: to prevent unjustified time-wise
24 extension of the right to exclude and multiple litigation.
25 Those are the reasons. Those are the only reasons. And the

1 Federal Circuit acknowledges that in footnote 5. The point of
2 the doctrine is about extensions of term. That's the point.

3 So is there an unjustified extension of term? Well,
4 here is a Federal Circuit case that makes it perfectly clear.

5 Now I'm up to slide 56. "The fundamental reason for the rule
6 against double patenting is to prevent unjustified time-wise
7 extension of the right to exclude. Only if the extension is
8 unjustified is a double patenting rejection appropriate."

9 They've got two problems here. First, there's no extension.
10 The '444 patent doesn't extend the term of the '471. And to
11 the extent there's a difference, it's a justified one. That's
12 I think the right way to analyze these things.

13 Those are just the two points I made earlier. Janssen
14 didn't cause the '471 patent to issue later and extend the term
15 under previous law. It didn't cause the '471 to have a later
16 priority date and extend the term under the URAA. And then
17 there are a handful of cases. I'm not going to dwell on them,
18 except to say that -- cases that circle around this issue, I
19 would say. There are three cases that I think analyze it the
20 way I think they should be. There's this most recent case in
21 California that I would disagree with. The cases that analyze
22 it I think correctly, District of Delaware case, *Brigham and*
23 *Women's Hospital*, similar factually to ours, before and after
24 patents, and essentially the later-issued earlier-expiring '244
25 patent in this picture here on slide 64.

1 THE COURT: So here. Let me have those two cases.

2 *Brigham and Women's*. And the other one is --

3 MR. DISKANT: Abbott.

4 THE COURT: Abbott. Those were factual scenarios
5 similar to the one we have here?

6 MR. DISKANT: Yes.

7 THE COURT: But the Federal Circuit criticized the
8 District Court in *Gilead* for relying on those decisions.

9 12:49 10 MR. DISKANT: Well, it should have because it had a
different fact pattern before it. It had two URAA patents.
11 But these cases analyze the problem we're talking about.

12 12 THE COURT: The fact that -- I mean, the Federal
13 Circuit didn't write if we had the facts in *Abbott* or *Brigham*
14 and *Women's*, we would come out differently. They would
15 criticize the District Court in *Gilead* for relying on them and
16 saying you didn't cite *Pfizer*, which comes out the other way.
17 So why shouldn't that signal to me how the Federal Circuit, at
18 least when it decided *Gilead* without the benefit of hearing
19 from you, would decide this case?

12:50 20 20 MR. DISKANT: I think because it just wasn't the issue
21 before it. We've been talking for quite a long time about
22 issues that are really unrelated to what it was thinking about,
23 and I don't ultimately see that discussion as anything more or
24 less than that's a different issue. There are two ways to
25 think about that issue. Maybe we'll face that one day. But

1 we're going to write a very careful decision that doesn't
2 decide that issue.

3 So I think, to me at least, that's the way to think
4 about what *Gilead* did. Because then, when you get into these
5 cases, they say things that I think are pretty wise and
6 unrelated to the issue in the *Gilead* case. So in the *Brigham*
7 and *Women's Hospital* case, first the court rejects the Patent
8 Office reasoning and basically says it doesn't explain why --

9 THE COURT: What page of this case?

12:51 10 MR. DISKANT: Oh, my. Let me see. It's page 225 of
11 the *Brigham and Women's* case. It's highlighted on the screen.
12 I don't know if you have the same printout that we have. It
13 basically rejects the argument that a later-issued patent with
14 a shorter term should be used to abridge the term of a valid
15 earlier-granted patent with a longer term.

16 THE COURT: There they're talking about *Pfizer*.

17 MR. DISKANT: Yes. It's not persuaded by *Pfizer*.

18 THE COURT: I might answer that question by saying
19 Janssen made a choice. It had the '471 with patent protection
12:52 20 until 2018. As you said, at a high level of generality,
21 inventors get narrower patents to protect against the
22 contentions of invalidity or infringement. So it made a
23 decision to do that. And having made that decision, knowing
24 that under double patenting law the two would be compared to
25 each other, it should -- it's fair, it's appropriate, to say

1 that the '444 is a reference to the '471 and therefore the '471
2 is now invalid.

3 MR. DISKANT: The reason I think that's not correct
4 is, basically -- and I apologize if I keep saying the same
5 thing, but I think it is the outcome determinative observation,
6 the '444 did not extend the term of the '471. That's all that
7 double patenting is about. It's not about policing patents
8 that have been obtained for multiple reasons. It's not about
9 whether you can or can't bring an infringement case after one
10 patent or another. It's not about the reasons that patents
11 were applied for. It's simply about, can you say that the '444
12 patent extended the term of the '471? And it did not.
13 Therefore, there is no double patenting issue.

14 And the court more or less says the same -- this is on
15 now page 225. And it says, you know, had the law not -- it's
16 focusing on the change in the law. Had the patent law not been
17 changed, the later-issuing '444 patent could have extended
18 beyond. So basically it's saying the only reason this one is
19 shorter, just like the only reason the '444 is shorter, is
20 because of the change in the law. And so you can't say that
21 the shorter patent, in our case the '444, in this case the
22 '244, "The '244 patent's term could not extend the patent
23 protection to which the plaintiffs were already entitled,"
24 likewise, the '444 could not extend the protection to which we
25 were already entitled on the '471, and therefore there's no

1 double patenting issue.

2 THE COURT: Okay. Do you want to speak briefly to
3 Abbott? And then we may have to break for lunch.

4 MR. DISKANT: Sure. Abbott, this is on slide 64, and
5 this is similar facts, different District Court in Delaware.
6 And likewise, the District Court does the same kind of analysis
7 that I've urged is correct. Abbott has obtained no time-wise
8 extension of the earlier-issued but later-expiring patent. The
9 term of the patent," the '471 in our case, "is the same as it
10 would have been if the '444 had never issued." And it goes on
11 to make again the same point I keep making. "Obviousness-type
12 doctrine double patenting is intended to address unjustifiable
13 extensions of patent term. Here there's no undeserved,
14 extended patent term resulting from the improper gamesmanship
15 by the patentee." All that has happened is an act of Congress
16 implementing international trade negotiations yields an earlier
17 expiration date. "Abbott has received no undeserved benefit,"
18 in its longer patent, just as we have received no undeserved
19 benefit with the '471.

20 The Phillips case which they cite is more or less to
21 the same effect. I can just wrap this up with the MLC case
22 that they gave us yesterday. I think its analysis is slender.
23 It has basically two sentences of analysis. One, it says, "The
24 fact that the patents in Gilead were governed by the URAA was
25 not relevant to the court's reasoning." I think that's

1 incorrect as we have seen. And "Gilead's holding was based on
2 the principle that when a patent expires, the public is free to
3 use it." And that's correct but only a generality, and this
4 does not address, as the other courts do, whether there was or
5 wasn't an unjustified extension of term.

6 So I've gone on a long ways, and I've got a couple of
7 random points to make, but I'm happy to break now.

8 THE COURT: Well, you've gone through 57 of the 80 --

9 MR. DISKANT: I'm deep.

12:57 10 THE COURT: -- slides you have.

11 MR. DISKANT: I think I'm down to 70 or so. I think,
12 by my count.

13 THE COURT: You're on 70?

14 MR. DISKANT: I've got just a little left. If you
15 want me to wrap it up again I can in three minutes or less, or
16 we can save it. There's not much here that I haven't already
17 said. Should I wrap it up?

18 THE COURT: Well, I want to try to think about how to
19 do this.

12:58 20 Mr. Hurst, are you going to want some time to respond?

21 MR. HURST: I will if you have questions or -- I mean,
22 if you've already reached the decision you think you're going
23 to reach, obviously I don't need to, but I'd be happy to.

24 THE COURT: I'll probably hear from you.

25 MR. HURST: Sure.

1 THE COURT: All right. I think we're going to stop
2 now. I'd like you to come back at 2:15. I want to make sure I
3 give you enough time to eat. I may decide this motion this
4 afternoon, but I may not, because I'm very interested in
5 hearing the reexam argument today. As I say, I haven't been as
6 immersed in that. So try to get back by 2:00, but if it's just
7 not possible, don't worry about it. And I'll try to get back
8 by 2:00, too. We'll finish this, and then I think we'll go
9 into the other argument while I would rather -- that's probably
12:59 10 what we'll do. Please be prepared to argue the reexam motion
11 when we finish this one. All right. Court is in recess.

12 (Recess taken 12:58 p.m. to 2:05 p.m.)

13 THE COURT: Good afternoon. If you'd like to continue
14 and conclude.

15 MR. DISKANT: I will do both, Your Honor. Thank you.
16 May I have the screen back again?

17 THE COURT: What slide are we on?

18 MR. DISKANT: This is 70. So when we broke, we were
19 talking about unjustified extension of patent term. Your Honor
02:05 20 was questioning about the expectations of the public and the
21 patentee and stability in the patent system.

22 So if we just look at the timeline, in September 2001
23 the '471 patent issued. At that time there was not a single
24 Federal Circuit case that suggested that it could possibly be
25 subject to a double patenting problem with respect to any

1 patent that issued afterwards. The only double patenting issue
2 relates to patents that issued before. And when we move on to
3 reexam issues this afternoon, those will be patents that are
4 issued before. Patents that issued after had nothing to do
5 with double patenting analysis insofar as the court was
6 concerned, the patentees, the public, anyone. So when the '444
7 patent was filed, it was going to issue later, and it did issue
8 later. As a consequence, it presented no double patenting
9 issue to anyone with respect to invalidating the '471. There
02:07 10 is and was a double patenting issue under then current law, and
11 it was the reverse issue. The question was, since the '471
12 already existed, the '444 patent might pose a double patenting
13 problem with respect to itself. And in terms of, you know, the
14 stable enforcement of the law and justified expectations of the
15 public, the Patent Office perceived that problem and enforced
16 it. The Patent Office rejected the '444 patent because of the
17 existence of the '471 patent. It's the opposite.

18 THE COURT: Well, they rejected it. Then what
19 happened?

02:07 20 MR. DISKANT: Then, so they rejected it for double
21 patenting, obviousness-type double patenting. Now, you ask why
22 would they do that when it's going to expire earlier? And the
23 reason is --

24 THE COURT: No, no. It got issued.

25 MR. DISKANT: It didn't get issued --

1 THE COURT: The '444?

2 MR. DISKANT: Yes, it did.

3 THE COURT: You're saying it was rejected. Something
4 happened and then it got issued.

5 MR. DISKANT: That's correct. That's what I'm going
6 to tell you. What happened is it got rejected. I'm addressing
7 why would it be rejected when it's going to expire earlier.
8 And the reason it gets rejected is because there's the other
9 double patenting problem, multiple lawsuits.

02:08 10 So in the record, and unfortunately I don't have a
11 slide, but it's docket 188, Exhibit A, you will see the
12 rejection of the '444 application in light of the '471 patent,
13 issued patent. That's the stable application of double
14 patenting law. The rejection goes to the problems with the
15 '444, not the '471.

16 Then Janssen responds to that rejection by filing a
17 terminal disclaimer. And it basically says -- well, obviously
18 not going to run past the '471, but it also says in the
19 terminal disclaimer, "We agree that this patent will be
02:09 20 enforceable only so long as it's commonly owned with the '471
21 patent, avoiding the risk of multiple lawsuits." And with that
22 terminal disclaimer, the '444 patent issues over the double
23 patenting objection. Well, double patenting objections don't
24 go both ways. One has a problem or the other one has the
25 problem. The problem, if there's any problem --

1 THE COURT: I think that -- Well, anyway. Go ahead.

2 MR. DISKANT: The problem, if there was a problem,
3 under stable application of settled law was with the '444
4 patent. There was no basis for anyone, Celltrion, Pfizer,
5 Hospira, any member of the public to look at the filing of the
6 '444 patent and think, Oh, that's going to invalidate the '471.
7 It couldn't possibly be under the law in 2001 or in 2004, and
8 indeed the first time the Federal Circuit said that a
9 later-issued patent could be used for double patenting
02:10 10 rejection was in *Gilead* in 2014. So when one thinks about the
11 stable -- that doesn't answer the question. It's just part of
12 the analysis. But as part of the analysis when one thinks
13 about the stable application of settled law and the justified
14 application of the parties, that's what they were.

15 THE COURT: I mean, I've been thinking about this over
16 lunch, too. Here you have one company that owns both patents,
17 and the patents overlap. There's the more general '471 patent
18 that includes the antibody that's specifically covered in the
19 '444. '444 expires in 2011. Under your analysis, and you
02:11 20 could be right, the '471 essentially extends the life of the
21 '444.

22 MR. DISKANT: No.

23 THE COURT: There's still a patent that covers the
24 antibody.

25 MR. DISKANT: The '471 patent exists on its own. It

1 issued in 2001. The entire world understood it would have 17
2 years of life. It has 17 years of life. The '444 patent is
3 gone. Their claims are not identical. They're patentably
4 indistinguishable, but they aren't identical. For all I know,
5 some hypothetical infringement case, we could win one and lose
6 the other. I'm not saying that's true. I don't know.

7 THE COURT: But *Gilead* talks about not extending the
8 life of patentably indistinguishable alternatives.

9 MR. DISKANT: That's correct.

02:12 10 THE COURT: This may -- I mean, this may be too
11 commonsensical -- well, anyway, keep going. This is useful.

12 MR. DISKANT: To me, that's the right question, but
13 the question is -- and before you can invalidate the '471 for
14 double patenting, we ask whether the patentee has done
15 something to extend its life unjustifiably.

16 THE COURT: But that's not the ultimate holding in
17 *Gilead*. The ultimate holding in *Gilead* is that a later-filed
18 patent can -- and I guess they don't say "always," but "can" in
19 the circumstances of that case -- be the reference for an
02:13 20 earlier-obtained patent, earlier-filed patent.

21 MR. DISKANT: Yeah, but *Gilead* also says in its
22 summary, "Because the obviousness-type double patenting
23 doctrine prohibits an inventor from extending his right to
24 exclude." And that's exactly what -- that's in the bottom of
25 the second paragraph of the opinion. That's exactly what

1 happened in *Gilead*. The right to exclude was extended because
2 the priority date was moved. And that extended --

3 THE COURT: All right. I think I understand.

4 MR. DISKANT: I'm repeating myself. Let me just wrap
5 up then.

6 Okay. Our argument is it doesn't extend. It's
7 reversing Congress's grant of a longer term. They've got to
8 engage on unjustified extension of patent term. I don't think
9 they do that. They have arguments about Janssen's possible
02:13 10 motivation in seeking the '444 patent. The only issue is
11 whether Janssen sought the '444 patent in some way that would
12 extend the term of the '471 and it didn't. And lastly, through
13 the terminal disclaimer, there's no risk of multiple
14 litigation.

15 So that's how we would analyze the case, Your Honor.
16 Thank you.

17 THE COURT: Thank you.

18 Would you like to respond?

19 MR. HURST: Yes, Your Honor. Can we put up our slide,
02:14 20 slide 3. The arguments that counsel made are familiar
21 arguments that were actually -- most of which were addressed
22 head on in *Gilead*, head on, including the argument that counsel
23 made about this extending the right to exclude. Counsel said
24 the question you should be considering, Your Honor, is whether
25 the '444 patent extended the life of the '471 patent. That's

1 not the issue. The issue is whether the '471 extends the life
2 of the '444 patent. That's the issue.

3 And literally, the argument that counsel made is
4 addressed right in the opinion. *Gilead* made the same argument
5 about looking at it in the reverse way, and the court declined
6 to do so.

7 Can I take just a little bit of time to walk through a
8 couple of points in *Gilead* I wanted to go to?

9 THE COURT: Okay. But actually, here. Just pause for
02:15 10 a second.

11 MR. HURST: Sure.

12 THE COURT: When you say the issue is whether the '471
13 impermissibly extends the life of the '444 -- that's somewhat
14 the way I began to think about it more over lunch -- why do you
15 say that's the proper way to frame the issue?

16 MR. HURST: Because under this bedrock principle that
17 has existed forever, the question you are asking is when a
18 patent expires, the public has the right to expect -- by the
19 way, it's the public's expectations that are critical here.
02:16 20 When a patent expires, under long-held principles, the public
21 has a right to practice that claimed invention and any obvious
22 modifications. And a patent owned by the same patent owner
23 that stands in the way of that right has been invalid for
24 double patenting since forever. And that's a situation we face
25 here. I wanted to show you --

1 THE COURT: The plaintiff says, No, we're not trying
2 to extend the '444. We're trying to, you know, get the
3 additional years we have a right to under the '471. Why is
4 that incorrect? Because the inventions are patentably
5 indistinct.

6 MR. HURST: Patentably indistinct and because the way
7 the principle has always worked is you look at the earlier-
8 expiring patent and you say to yourself, at that point in time
9 the public has the right to say, Okay, when that patent
02:17 10 expires -- it was part of the bargain, it was part of the deal
11 that the patent owner made. When that patent expires, I, at
12 the public level, have a right to practice that invention or
13 any obvious modifications. And the key for double patenting is
14 a commonly owned patent can't stand in the way. And if it
15 does, it's invalid for double patenting. I think it's extra
16 clear. Some of your discussion with opposing counsel I thought
17 was really helpful --

18 THE COURT: Thank you.

19 MR. HURST: -- because I started to focus on some of
02:17 20 the concerns you were raising and some of the points that
21 counsel was making. And if you go to -- there's a chart, Your
22 Honor, just to show you how indistinguishable these cases are
23 in principle, in principle. It's on page 1210.

24 THE COURT: I have the chart on 1211.

25 MR. HURST: Okay. I have a Westlaw printout. I'm

1 trying to match up my numbers.

2 But if you look at this chart, you'll see the '483 was
3 the later-expiring patent, that was the one that was challenged
4 and invalidated. It's a longer patent, 18-year patent. It
5 issued earlier. The '375 patent issued later, expired earlier.
6 It was only a 16-year patent. Okay? So for our purposes, the
7 '375 is akin to the '444, and the '483 is akin to the '471.

8 Now look at the Court's reasoning. If you go to --
9 and this is where *Gilead*'s counsel makes the same argument as
02:18 10 Janssen's counsel is making here. If you go to -- I hope this
11 is the right page, Your Honor -- 1214. Towards the bottom of
12 the paragraph that begins with "In that principle."

13 THE COURT: I'm sorry?

14 MR. HURST: There's a paragraph that says "*Gilead*'s
15 response." It's right above that.

16 THE COURT: Okay.

17 MR. HURST: It says, "The '483 patent," that's the
18 later-expiring patent, "therefore extends the inventor's term
19 of exclusivity" --

02:19 20 THE COURT: Hold on a second. It's above the --

21 MR. HURST: There's two headnotes, 6 and 7.

22 THE COURT: Yes.

23 MR. HURST: It's at the bottom of that paragraph about
24 two sentences from the beginning.

25 THE COURT: Okay.

1 MR. HURST: So it says, "The '483 patent," that's
2 equivalent to our '471, "therefore extends the inventor's term
3 of exclusivity on obvious variants of the claimed invention in
4 the '375," that's equivalent to our '444, "for an additional 22
5 months past the expiration of the '375." That plainly violates
6 the public's right -- this is the public's expectation -- the
7 public's right to use the invention claimed in the '375 patent
8 and all obvious variants of it after the '375 patent expires.
9 You can replace '444 for '375 and '471 for '483, and it would
02:20 10 apply directly.

11 Here is the point I wanted to emphasize. The argument
12 Janssen is making, Your Honor, is exactly the exact argument
13 that *Gilead* made in the next paragraph. *Gilead*'s response is
14 simply that the '375 patent -- now they go in reverse -- "the
15 '375 patent in no way extends the terms of exclusivity for the
16 '483 patent." That's literally the argument that Janssen's
17 counsel made. He said in no way does the '444 patent extend
18 the life of the '471 patent. The Federal Circuit goes on to
19 reject that argument. It recognizes that *Gilead* argues that we
02:21 20 should focus on the potential term extension for the '483
21 patent instead of the '375 patent because the '483 patent
22 issued first. Again, that's the argument that Janssen just
23 made. And the court says, "We see little import here to the
24 fact that the '483 patent issued first." Then you go on to the
25 part of the opinion that you read earlier and you asked some

1 questions about, Your Honor.

2 THE COURT: What about the line a little further? It
3 says, "Those cases dealt with patents to which the URAA did not
4 apply."

5 MR. HURST: Right. So what they're saying here is
6 pre-URAA, the rules weren't different, but the courts often
7 talked about earlier-issued and later-issued as proxies for
8 earlier-expired, later-expired. And that's clear to me, Your
9 Honor. If you go to the next -- they cite a series of cases,
02:22 10 right? Then if you go to the bottom of that paragraph, it
11 says, "As discussed above, the primary ill avoided by
12 enforcement of the double patenting doctrine is restriction on
13 the public's use, the public's rights, freedom to use the
14 invention claimed in a patent and all obvious modifications of
15 it after that patent expired," with italics. Therefore, they
16 say the focus on controlling the patent term of a later-issued
17 patent in those cases, it makes perfect sense because before
18 the URAA issuance dates and expiration dates matched up. I
19 just want to go to the bedrock principle. They say, "As
02:22 20 discussed above," Your Honor, you know what's discussed above?
21 It's that bedrock principle we just talked about. And if you
22 want to take a look at it, it's page 1214, headnote 5.

23 "It's a bedrock principle of our patent system" --

24 THE COURT: I have that.

25 MR. HURST: My point is that principle is the

1 principle that controlled in *Gilead* to invalidate the
2 later-expiring patent. That bedrock principle is the principle
3 that should control here to invalidate the '471 patent. And
4 one thing that counsel said a number of times is nobody could
5 have ever envisioned this circumstance when they took the '444
6 patent. Who could have ever thought, right? That bedrock
7 principle existed for 100 years, over. And it is literally the
8 principle that *Gilead* relied on. So I hear counsel saying
9 that, but any time two patents are issued that have patentably
02:24 10 indistinct inventions, you have to recognize that the later
11 patent, later-expiring patent is in jeopardy unless you can
12 rely on something like a safe harbor. And here they can't.

13 THE COURT: Okay.

14 MR. HURST: The last thing I just want to say real
15 quickly, Your Honor, is in terms of what Congress had in mind.
16 You talked a little bit about what did Congress have in mind
17 when they issued this statute. Congress issued a statute that
18 didn't say one word about comparing patents or the validity of
19 patents when compared. It literally is a mechanical,
02:24 20 Here-is-your-patent term.

21 Double patenting, Your Honor, it is a judicially
22 created doctrine. It was created by the Supreme Court. It's
23 been enforced by the courts. It has nothing to do with
24 Congress. Congress never -- as far as I know, Congress has
25 never spoken to double patenting, and it didn't do so in this

1 case through GATT. It was silent on it, I think counsel
2 correctly acknowledged. And therefore the longstanding
3 principles of double patenting ought to control this case.

4 Unless you have questions --

5 THE COURT: No, I don't think so. I do want to move
6 to the reexamination rather than try to decide this now. I
7 want to take a brief break so I can get reorganized, and then
8 we'll go. Thank you.

9 (Recess taken 2:24 p.m. to 2:37 p.m.)

02:36 10 THE COURT: All right. Now we'll move to the
11 reexamination motion for summary judgment that the defendants
12 have brought. I haven't -- I've studied this one but not as
13 deeply as the first.

14 My very tentative view is that the defendant is
15 entitled to prevail on this motion. I have some questions --
16 well, generally, just to be as transparent as possible so you
17 can address it, it's my tentative view that because the
18 application at issue is a continuation-in-part and not a
19 divisional application on its face, it's not entitled to the
02:38 20 protection of the Section 121 safe harbor.

21 I think it's not disputed that if a one-way
22 obviousness test applies, the plaintiff flunks. With regard to
23 the two-way obviousness test, I have some questions. As I
24 understand it, the two-way obviousness test applies when a
25 patent for a basic invention is filed first and later there's

1 an application for an improvement that's issued first. I
2 believe that here the inventor filed for the three patents
3 involved in this on the very same day, or at least two out of
4 the three, the '471 and the '272. So I wonder in these
5 circumstances whether the two-way double patenting issue is
6 implicated. Unlike the Patent Office at the moment, I don't
7 think *Berg* decided that issue. I think *Berg* was decided on
8 other grounds. But that's one question.

9 Then I actually have a question of whether the
02:39 10 two-way -- you know, whether the two-way test should be applied
11 as ripe for decision on a motion for summary judgment. I know
12 that under *Hubbell*, 709 F.3d at 1149, the two-way test is
13 ultimately a question of law. However, as I understand it, or
14 possibly misunderstand it, the issue under the two-way test is
15 whether the PTO was solely responsible for deciding -- for the
16 fact that the second-filed application was issued first or
17 whether the applicant caused or contributed to the delay.

18 That's a question of fact, I believe. And as my
19 friend and colleague Judge Bennett wrote in *Iowa, in Engineered*
02:40 20 *Products*, 225 F. Supp. 2d 1069 at 1089, it's possible that a
21 material fact with regard to the applicability of the two-way
22 test is implicated. This type of issue may be more familiar to
23 me than to you. It's what judges confront when we have to
24 decide whether a police officer has qualified immunity in a
25 section 1983 case. And if there are material facts in

1 dispute -- qualified immunity is an issue of law, but if there
2 are material facts in dispute, I have the jury decide the
3 facts, and then relying on those facts, I make the decision of
4 law. So that's a question I have here that I don't think the
5 parties have addressed.

6 The issue may be material to whether the two-way test
7 applies, although there are also -- although I usually don't
8 give advisory opinions, if that is a disputed material fact, it
9 could perhaps be leapfrogged, imprudently be leapfrogged for me
02:42 10 to decide if the plaintiff fails the two-way test even if it's
11 involved. I mean, my general sense of this, and it's part of
12 the reason we're spending so much time on it and why I want to
13 decide it orally, is that a prompt decision is important to
14 you. Its certainty is important. And somebody's probably
15 going to appeal this if you don't settle your disputes. So
16 maybe I would tell you how I would decide the two-way
17 obviousness issue if it were ripe to be decided.

18 Then I want to know whether the parties agree the
19 two-way test is an objective test, not a subjective test.
02:43 20 That's how I read, at the moment, the Federal Circuit's
21 decision in *Fallaux*, 564 F.3d 1313 at 1317. The Federal
22 Circuit there says, "Nefarious intent is not required." It
23 looks like it's focusing on what happened as a result of the
24 inventor's, the patentee's conduct, not what the motive for the
25 conduct was.

1 And then, the defendant says it's undisputed that the
2 plaintiff -- and the plaintiff would agree -- that the '471 is
3 invalid under a one-way test. I would be interested in
4 clarification or confirmation concerning that. So that's my
5 present state of mind.

6 MR. HURST: Thank you.

7 THE COURT: Would you like to go first again?

8 MR. HURST: Sure. Thank you, Your Honor.

9 THE COURT: We have another set of slides that we'll
02:45 10 make Exhibit C.

11 MR. HURST: Just to start, I think we've already
12 confirmed this, at least currently the '471 patent is before
13 the Patent Office and declared or deemed to be invalid over the
14 '195 and '272 patents.

15 There's three questions. We think they're all
16 questions of law. I have them up here on the screen. One is
17 does the safe harbor apply; two, one-way versus two-way; and
18 three, if two-way applies, can you consider the specification
19 of the '471 patent. And that we think is dispositive as well.
02:45 20 So you outlined it correctly, I believe, Your Honor, as I heard
21 it.

22 The way it would work is if we prevail on issue one,
23 safe harbor, then if we prevail on either issue two or issue
24 three, we would prevail.

25 THE COURT: On either issue?

1 MR. HURST: Yeah, because say the safe harbor doesn't
2 apply. Then you go to question two. If the one-way test
3 applies to either --

4 THE COURT: Hold on a second. What slide is that?

5 MR. HURST: I'm sorry, slide 3.

6 THE COURT: All right.

7 MR. HURST: So if the one-way test applies to either
8 of the referenced patents, including the one filed on the same
9 day, we would prevail. We wouldn't have to go any further. If
02:46 10 you decide that the two-way test must be applied to both
11 referenced patents, we could still prevail if we prevailed
12 under the two-way test.

13 Now I'm going to talk about how we think we'd do.

14 THE COURT: What are the two -- hold on a second. The
15 two patents you say were filed on the same day are what?

16 MR. HURST: '272 and '471.

17 THE COURT: They were filed February 4, 1994?

18 MR. HURST: That's correct.

19 THE COURT: When was the '452 filed?

02:47 20 MR. HURST: I believe September of '94, although I'm
21 not absolutely certain.

22 THE COURT: I think in your opening brief at page 13
23 you tell me that the '452 is also filed February 4. I don't
24 know whether this makes any difference.

25 MR. HURST: It might have been a mistake. It wouldn't

1 make a difference, right, because we only need one patent filed
2 on the same day for us to prevail. If we said that, Your
3 Honor, it was a mistake. It's October of '94.

4 THE COURT: So the '452 is October.

5 MR. HURST: You said '452? There are two patents.

6 THE COURT: Let me see the brief I just cited.

7 I see. Maybe I was looking at the '452 instead of the
8 '195. I see. Is it the '195 that's --

9 MR. HURST: The '195 was filed in October of 1994,
02:48 10 October 18, and the '272 patent was filed on February 4, 1994,
11 same day as the '471 patent.

12 THE COURT: All right.

13 MR. HURST: Should I proceed?

14 THE COURT: Go ahead.

15 MR. HURST: That's the way we think it will shake out.
16 If we prevail on issue one and either issue two or three, we
17 should prevail on summary judgment. So let's just start at
18 issue one. You tell me if I'm giving you too much background,
19 but I was going to give a little bit of context.

02:49 20 THE COURT: Go ahead.

21 MR. HURST: In terms of the basics of patent
22 prosecution, '471 was filed as a continuation-in-part. There's
23 four possible applications you can file in the Patent Office,
24 the original one, continuation, continuation-in-part,
25 divisional. A continuation-in-part adds new matter, as I'm

1 sure you know. You take the original application, you amend
2 it, you add new stuff, then you have to call it a
3 continuation-in-part. Both the continuation and a divisional
4 are just copies of the original. But they're labeled
5 differently. But in neither case is there any new matter.

6 So why do you have two types of applications? Your
7 Honor, the divisional is specially designed to deal with this
8 restriction requirement situation, where you get a restriction
9 requirement, and you file a divisional in order to take
02:50 10 advantage of the safe harbor.

11 Am I getting too basic here?

12 THE COURT: No, not at all.

13 MR. HURST: All right. So here is part of the text of
14 Section 121, on its face, it says it only applies with respect
15 to the original -- so here is how it happens. You go to the
16 Patent Office. You file one application. Patent Office says
17 to you, as a patent holder, You know something, guys? You have
18 more than one invention here. So you have to break them off.

19 THE COURT: More than one invention that might or
02:50 20 might not be patentable?

21 MR. HURST: That's true.

22 THE COURT: I'm just trying to make sure I understand
23 it.

24 MR. HURST: Totally, right. You have more than one
25 subject matter for invention analysis. So here is one example.

1 One example might be you file a patent that says, I came up
2 with a brand new chemical compound, and you say, My new
3 chemical compound can be used to treat the common cold. Patent
4 Office might say, That's two inventions, new chemical compound,
5 new way to use, so divide them up. The way you're supposed to
6 proceed once you get that restriction requirement is you can
7 keep your common chemical compound and original application,
8 but then you have to file a divisional to take advantage of 121
9 on using your new chemical compound to treat the common cold.

02:51 10 THE COURT: And a divisional would add no new
11 material?

12 MR. HURST: No. Divisional should add no new
13 material. It cannot.

14 THE COURT: If you add the new material it's a
15 continuation-in-part?

16 MR. HURST: That's right, that's right. Now, this
17 issue, Your Honor -- this is a statute issued by Congress. So
18 I understand you don't have a big load of patent cases, but
19 this is actually a statutory interpretation issue: Does
02:52 20 divisional application under the statute mean divisional
21 application.

22 THE COURT: Okay. Go ahead.

23 MR. HURST: I don't want to interrupt.

24 THE COURT: No. Go ahead.

25 MR. HURST: There's three cases, *Pfizer*, *Amgen* and

1 *G.D. Searle.* All three cases, Your Honor, treat this as a
2 traditional matter of statutory interpretation. They say,
3 What's the plain language of the statute? They literally look
4 at the legislative history. They literally say, What were the
5 circumstances when Congress enacted the statute? Did they know
6 there were these four different kinds of applications? And if
7 so, the plain meaning has to control. That's what *Pfizer* said
8 in 2008. The same argument that Janssen is making here, *Pfizer*
9 argued that the terms "divisional" and "continuation-in-
02:53 10 part" -- this is slide 7, that the terms "divisional" and
11 "continuation-in-part" are merely labels used for
12 administrative convenience and that accordingly, although after
13 the restriction requirement they filed a CIP, they said it's in
14 effect a divisional because it was filed in response to a
15 restriction requirement.

16 How did *Pfizer* resolve the issue? Legislative
17 history, circumstances when the statute was enacted, and they
18 relied on the plain language. Section 121 explicitly refers to
19 divisional applications. That safe harbor, by its literal
02:53 20 terms, protects only divisional applications. So they treated
21 it as a straightforward statutory interpretation exercise.

22 So with respect to *Pfizer*, one of the things that
23 Janssen is arguing to try to distinguish *Pfizer* is to say that
24 in the *Pfizer* case, the new matter that was added to the CIP in
25 *Pfizer* was important. Here they say the new matter that was

1 included in their CIP was unimportant. So in *Pfizer*, you
2 couldn't ignore the new matter because it was important, and
3 therefore it had to be treated as a CIP. Here, in this case,
4 they're saying the new matter was unimportant, and therefore
5 you can treat that CIP as a divisional. That's the argument
6 that they made.

7 But *Pfizer* rejected -- *Pfizer*'s rationale and
8 rejection of treating a CIP as a divisional had nothing to do
9 with the importance of the new matter. It literally had to do
02:54 10 with when Congress said "divisional application," did Congress
11 mean divisional application? And the answer was yes.

12 THE COURT: Let's see. What page of --

13 MR. HURST: 1362.

14 THE COURT: 1362. Okay.

15 MR. HURST: They say. "We conclude that the
16 protection afforded by Section 121 to applications filed as a
17 result of a restriction requirement is limited to divisional
18 applications," and their analysis was as simple as this one
19 was. It was a CIP, not a divisional application. The decision
02:56 20 did not in turn turn on the importance of the new matter.
21 That's even more clear, though, from *Amgen*, which was decided a
22 year later. This is slide 9.

23 THE COURT: Just one second.

24 MR. HURST: Take your time, Your Honor.

25 THE COURT: *Amgen* at 1353?

1 MR. HURST: Yes.

2 THE COURT: Go ahead.

3 MR. HURST: So the reason *Amgen* we believe refutes
4 this argument about a need to focus on the importance of the
5 new matter is because *Amgen* dealt with a continuation. There
6 wasn't new matter. So *Amgen* is really close to a divisional in
7 the sense that both the continuation application and a
8 divisional application had no new matter. It's literally just
9 the title. And in this case in response to restriction
02:58 10 requirement, the patent owner filed a continuation rather than
11 a divisional.

12 THE COURT: And what did Janssen file, a continuation
13 or continuation-in-part?

14 MR. HURST: Continuation-in-part.

15 THE COURT: That's what I thought.

16 MR. HURST: So once removed. And how did *Amgen* -- if
17 equities were to control here, right? This seems like it's not
18 even -- there's no change to the application. They literally
19 could have just said "divisional" rather than "continuation,"
02:58 20 and they could have taken advantage of Section 121. How did
21 the court decide it? They read the statute. The statute on
22 its face applies only to divisional applications, and a
23 continuation application, like a continuation application in
24 part, like *Pfizer*, is not a divisional. It was really that
25 simple and straightforward.

1 They address the argument -- they went on to address
2 the argument that Janssen is making here about, even though it
3 was labeled as a continuation, you ought to treat it as a
4 divisional. This is *Amgen* at 1354. That's the argument *Amgen*
5 made. They said, Look, we could have filed these continuation
6 applications as divisional applications, so you should treat
7 them as such. And the court said, "We decline to construe, in
8 'divisional application' in Section 121 to encompass *Amgen*'s
9 properly filed, properly designated continuation application."

02:59 10 This is slide 10. That's what we have here.

11 Janssen filed a properly filed and a properly
12 designated continuation application in part. *Amgen* filed a
13 properly filed and properly designated continuation
14 application, and in neither instance does that meet the plain
15 language of Section 121, which says "divisional application."
16 The court in *Amgen* goes on to explain how close divisionals and
17 continuation applications are, at slide 10. And they talk
18 about this. They say, "Unlike a continuation-in-part
19 application, a continuation application can satisfy the
03:00 20 definition of divisional application in MPEP 201." Why?
21 Because it does not add new matter. So whereas a continuation
22 and divisional applications are limited to subject matter
23 disclosed in the earlier application, CIP adds matter.

24 What did the court say? This is the last line there.
25 They say, "This distinction, however, does not justify

1 departing from a strict application of the plain language of
2 Section 121, which affords its benefit to divisional
3 applications." So they consider this whole analysis of plain
4 language analysis under the statute, and that ought to control.

5 Now, so there's -- what else does Janssen say?

6 Janssen, Your Honor, as you know, they went to the Patent
7 Office during this reexam. So, well after patent issuance, the
8 public was entitled to rely on the fact that the '471 was not
9 entitled to safe harbor protection because it didn't have a
03:01 10 continuation -- it wasn't filed as a divisional, right? But
11 they altered the application during the reexamination. They
12 got an amendment. And the amendment was to delete all the new
13 matter and change the label from a CIP to a divisional. So
14 right now, in the Patent Office proceedings, they amended the
15 original application well after patent issuance on the '471
16 patent.

17 That doesn't matter for a variety of reasons, but one
18 particular reason for Your Honor's benefit is that amendment on
19 slide 11, it can't take effect until the reexamination is over.
03:02 20 So for this proceeding here, your assumption, you should treat
21 the '471 patent as something that was issued off a CIP, because
22 the amendment that Janssen has tried in the Patent Office --
23 tried to get in the Patent Office does not take effect until
24 that reexamination is over, and who knows when that will be.

25 There's a CFR regulation on that that we cite at page 11. I

1 don't think there's any dispute about that. Both parties have
2 talked about this fact.

3 But even if you were to consider the amendment that
4 has now occurred in the Patent Office, it wouldn't make any
5 difference because of the *Searle* case. The *Searle* case which
6 was just decided in 2015, it was the same circumstance. What
7 happened is, the patent was issued off a CIP. It was actually
8 the same patent issue in the *Pfizer* case. The patent was
9 issued off of a CIP. The patent owner goes back to the Patent
03:03 10 Office and says, Let me amend my patent application. I'm going
11 to amend it by deleting new matter, so it goes from a CIP, and
12 I'm going to change the label from CIP to divisional. So they
13 amend it back to what it would have if they had done it right
14 the first time, giving them the benefit of 121. And the
15 Federal Circuit said no. They said -- there's a new litigation
16 of the patent, the Federal Circuit said, "Despite being
17 designated as such in the reissue patent," as a divisional it
18 doesn't change anything because, "Simply deleting that new
19 matter from the reissue patent does not retroactively alter the
03:03 20 nature," of the original application, which was filed as a CIP.
21 "Because neither of the '068 patent's application is a division
22 of the original '594 application, Section 121 does not apply."

23 THE COURT: There's also a fairness issue here.

24 Go ahead.

25 MR. HURST: There's also a fairness issue here because

1 the public, when making decisions, business decisions about
2 which products to pursue and not pursue, are entitled to look
3 at issued patents for what they are, and the '471 patent did
4 not have safe harbor protection. And to try to somehow give it
5 safe harbor protection not only well after the fact but like
6 years after the fact, years after the '471 patent has already
7 been in existence for quite some time would be unfair, so I
8 think the *Searle* case got it right.

9 Moreover, a future, a change, belated change to the
03:05 10 application, switching it from a CIP to a divisional, cannot
11 change historical facts, and because you can't change those
12 historical facts, you can never get yourself under 121. Here
13 is why I say that. In response to a restriction requirement,
14 you have to file the divisional application. They didn't do
15 that. They filed a CIP. That's an historical fact you can't
16 change after the fact, number one.

17 Number two, that divisional application has to be
18 filed before the issuance of the patent on the other
19 application. This would be the '272 one in '95. They didn't
03:05 20 do that either. Temporally under the statute doing it now here
21 in 2016 would be too late.

22 Now, one last thing, in some of the briefs, Your
23 Honor, Janssen has suggested that you ought not decide this
24 issue. You should wait until the Patent Office proceedings
25 move forward.

1 THE COURT: I already denied the stay.

2 MR. HURST: I believe that's correct. Janssen -- I
3 know that's correct. Janssen said that, Well, if your decision
4 could be mooted by what happens in the Patent Office. That's
5 not true. If you were to invalidate the '471 patent based on
6 the existing record, this dispute is over. We cited a case on
7 that to send you. That case is a case where they lost the
8 case, then a new patent emerged from reexamination. The
9 Federal Circuit says you can't start over. You can't have a
03:06 10 second bite at the apple. You've lost, so the new patent out
11 of the reexamination can't change anything.

12 THE COURT: Will the reexamination continue if I find
13 this invalid?

14 MR. HURST: I believe that it would not. I believe
15 that it would not because once you declare -- here is what I
16 think. If you were to declare the patent invalid, that
17 information would have to go to the Patent Office. So it would
18 stand invalidated. I believe what they could do is stay those
19 proceedings until your case inevitably is going to go up to the
03:07 20 Federal Circuit. I think they can do that, but there would be
21 no reason for them to continue because the patent would stand
22 invalid.

23 You had a conversation with Mr. Diskant about this
24 earlier, and we just thought it was helpful to put this
25 exchange in the record. It's on page 15. You asked this

1 question to Mr. Diskant. You said, Let's say I denied the stay
2 and granted summary judgment and then the PTO finds that the
3 amended patent is valid, then I suppose you could get -- you
4 could bring a new suit, a prospective suit at a minimum. And
5 Mr. Diskant says correctly, We believe under the case law, no,
6 we would completely lose. If Your Honor invalidated the patent
7 based on the earlier prosecution history without considering
8 the new change approved by the PTO to call the patent invalid,
9 the PTO proceedings would end, and we would lose our patent. I
03:08 10 believe that to be true. I think he had it right.

11 THE COURT: There's one thing I should have asked at
12 the threshold, which I think I know the answer to. If you
13 prevail on the *Gilead* motion and the Federal Circuit agrees
14 with me, the reexamination motion is moot, isn't it? You have
15 two grounds, and the other way around, too.

16 MR. HURST: We have two grounds. That's true, yeah,
17 that's true. So it's not uncommon in patent cases where a
18 patent gets appealed and it's declared invalid on multiple
19 different grounds. And the Federal Circuit typically addresses
03:08 20 all the grounds, but you only need one to win.

21 Okay. So one last thing that I probably should
22 address. Janssen has suggested that during the 1990s, the
23 practice in the Patent Office was that you didn't really need
24 to file a divisional application to take advantage of safe
25 harbor. They said it was the practice back in the '90s -- they

1 have an affidavit on this -- you could do a CIP if you wanted a
2 continuation and people didn't really care which application
3 was filed. We don't agree with that. We think the *Pfizer* case
4 actually references a bunch of Patent Office decisions agreeing
5 with their decision, so we don't agree with that. But it also
6 doesn't matter.

7 So what the practice was in the '90s is not relevant
8 to Your Honor's decision for sort of fundamental jurisprudence
9 issues. It's a principle -- we have a couple of cases up here
03:09 10 on slide 17. But the principle that judicial decisions operate
11 retrospectively is familiar to every law student. Once *Pfizer*
12 decided that 121 means what it says, it's got to be a
13 divisional application, that's the rule. And even if *Pfizer*
14 had changed the law, which we do not believe they did, but even
15 if *Pfizer* had changed the law, that's the law that controls in
16 this case. So it does not matter at all what people thought
17 the law might have been in the 1990s.

18 And then we have a Supreme Court case here, a quote
19 from Harper, which it really is a fundamental jurisprudence.
03:10 20 "When this court applies a rule of federal law to the parties
21 before it, that rule is the controlling interpretation of
22 federal law and must be given full retroactive effect in all
23 cases still open or on direct review as to all events
24 regardless whether such events predate or post-date our
25 announcement of the rule." So applied here, the *Pfizer* rule

1 applies even if it was a change in the law, even if it was
2 different from what people thought in the '90s, and we really
3 don't think it was.

4 So that brings us to, if you were to agree on the safe
5 harbor, then you get to the one whether to apply one-way versus
6 two-way. So I'm at slide 18. Okay. So I was going to sort of
7 explain why one-way versus two-way makes a difference. Let
8 me -- maybe it just helps, real briefly.

9 The way this normally comes up, Your Honor, is where
03:11 10 you have your basic invention. You know, say you invent a new
11 car engine where you get 60 miles a gallon. So you file an
12 application. You keep working on your car engine, and you end
13 up creating a new one with a new invention that gets you 100
14 miles per gallon. When you go to the Patent Office, your new
15 invention is going to be patentable over your old one, right?

16 But what if they reverse, right? Your new
17 100-mile-an-hour engine is going to be patentable over
18 60-mile-an-hour -- I'm assuming it's a new invention to get the
19 extra 40 miles.

03:12 20 But what happens if it gets reversed in the Patent
21 Office, right, and even though you filed for your improvement
22 patent a year after your basic patent, what if it gets
23 reversed? Well, then the later-expiring patent would be the
24 basic patent, so your 60-mile-an-hour would end up being the
25 later-expiring patent, and it would actually, through a one-way

1 test, be invalid, right? Because the 60-mile-an-hour-engine
2 would be obvious from the 100-mile-an-hour invention, right?
3 So that's when this all comes up.

4 But the key is, the key point is it's when you're
5 applying for basic patents before your improvement patents and
6 there's a reversal in the Patent Office.

7 Here, if you were to decide -- that didn't happen for
8 one of the two patents here, which is why I say that. Here
9 there's no dispute; Janssen admits that they're not contesting
03:13 10 that if you were to decide the one-way test applies, the '471
11 patent is invalid. The two-way test, Your Honor, is
12 extraordinarily rare. We have a bunch of cases that call it a
13 narrow exception, applies in a narrow set of circumstances.

14 THE COURT: Okay. So ordinarily the one-way test
15 applies.

16 MR. HURST: Not only ordinarily but, like,
17 extraordinarily --

18 THE COURT: Almost always you say. What is the
19 one-way test?

03:14 20 MR. HURST: The one-way test would only ask, would
21 only ask, whether the '471 invention is patentably distinct
22 from the '272 or the '195. So that only asks that question.

23 THE COURT: And the answer to that is?

24 MR. HURST: It's not patentably distinct. It's not
25 disputed.

1 THE COURT: And the plaintiff concedes that?

2 MR. HURST: That's right.

3 That's my 100-miles-per-gallon engine versus --
4 one-way versus the 60-mile-an-hour, it's going to survive, but
5 if you reversed it, it wouldn't. So it can make a difference
6 sometimes. We don't think it makes a difference here, because
7 here, you have to ask the reverse question as well if you get
8 the two-way test, and we think you do not.

9 Okay. The Federal Circuit has applied this only once
03:15 10 about 25 years ago.

11 THE COURT: It's only been applied once?

12 MR. HURST: Only once since its existence, right?

13 There used to be the CCP before the Federal Circuit. So I
14 believe since the Federal Circuit was created in 1983, it
15 has -- I believe it has once -- if it's been more than once,
16 it's only going to be once or twice, but I believe it's only
17 been once.

18 But here is the test, and there's really two parts to
19 it. The two-way test is only appropriate -- and this is from
03:16 20 -- you can find the same quote in many different cases, but
21 it's slide 22. It's "only appropriate in the unusual
22 circumstance where the PTO is solely responsible" -- solely
23 responsible -- "for the delay in causing the second-filed
24 application to issue prior to the first."

25 So one key thing is, Your Honor, you don't get out of

1 the starting gates unless you have a second-filed application
2 that issued prior to a first-filed application. So they have
3 to come out of the Patent Office in the reverse order. That's
4 where, in our view, Your Honor, Janssen doesn't get out of the
5 starting gates with respect to the '272 patent because there's
6 been no reversal. They filed them on the same day.

7 THE COURT: They filed two of them the same day.

8 MR. HURST: That's right. They filed the '471 and the
9 '272 on the same day. So you don't really -- you do not get
03:17 10 into a question of whether two-way or one-way applies because
11 you don't have the reversal that's required for you to get into
12 the two-way test.

13 THE COURT: Why isn't that too mechanical or
14 formulaic?

15 MR. HURST: Well, I would say it this way. The
16 two-way test only arose to address these reversals where your
17 later-filed improvement patent ends up getting issued before
18 your earlier-filed basic patent. So if you have that reversal,
19 in rare circumstances, if it's all the PTO's fault, then you
03:17 20 get to take advantage of the two-way test.

21 But every case, I think every case that talks about
22 the two-way test will refer temporally to the first-filed
23 application versus the second-filed application. We have not
24 found -- and we did look. We looked exhaustively for cases
25 that applied the two-way test or even considered whether to

1 apply the two-test where two applications were filed on the
2 same day, and we haven't found any. The closest is *Berg*, and
3 *Berg* obviously declined to apply.

4 THE COURT: What were the facts of *Berg*?

5 MR. HURST: It was a situation in *Berg* where the
6 applicant filed two applications on the same day, and there
7 were two components to the decision. One is the court said,
8 Well, you made the decision to file separate applications, so
9 you took the risk of doing so. But secondly, they pointed out
03:18 10 that they were filed on the same day. So there had been no
11 reversal. And I have the quote from the case.

12 THE COURT: Where is that?

13 You have the quote in --

14 MR. HURST: In my deck. Can I quickly go to the MPEP
15 and then go to *Berg*? Because I think it's important.

16 THE COURT: Hold on a second.

17 MR. HURST: Sure.

18 THE COURT: What slide are you on now?

19 MR. HURST: 24, *Berg*.

03:19 20 THE COURT: Go ahead.

21 MR. HURST: So this is the Manual of Patent Examining
22 Procedures. It's the bible for how to examine patents in a
23 Patent Office, and it's updated regularly. There's extensive
24 citation to Federal Circuit cases, how they're interpreted, how
25 they're to be applied. So this is a government agency, the

1 Patent Office's work product here, deciding what *Berg* means.
2 And here is what it says. Issued July 1998, so shortly after
3 *Berg* came out. It cites *Berg*. It says, "If both applications
4 are filed on the same day, only a one-way determination of
5 distinctiveness is needed." You don't even have to get to
6 trying to decide whether or not it was appropriate to do the
7 unusual two-way test. You stop there.

8 THE COURT: Hold on just a second.

9 Let's see. So the Patent Office document, the MPEP,
03:22 10 section 804, cites *Berg* for the proposition that you don't use
11 the two-way test if the applications were filed on the same
12 day, right?

13 MR. HURST: That's correct, Your Honor.

14 THE COURT: But *Berg* at 1433 appears not to have
15 relied on the fact that they filed -- two applications were
16 filed the same day. It says, "Although the decision of the
17 Board affirming the application of the one-way test rather than
18 the two-way test to *Berg*'s application is correct, we hold,
19 however, that this case is not appropriate for application of a
03:23 20 control prosecution rates analysis to determine whether *Berg* is
21 entitled to the two-way test. Rather we base our affirmance on
22 the second stated rationale of the Board: because *Berg* could
23 have filed the claims of its second application in a single
24 application and it simply chose to file two applications
25 despite nearly identical disclosures, *Berg* is not entitled to

1 the two-way test."

2 MR. HURST: No question about it. Important to this
3 decision was the fact that *Berg* could have filed in a single
4 application but they instead filed them in separate
5 applications. Take a look at 1434.

6 THE COURT: 1434.

7 MR. HURST: Actually, why don't you go to the bottom
8 of 1433.

9 THE COURT: Go ahead.

03:24 10 MR. HURST: *Braat* I believe is the case I know of
11 where the Federal Circuit applied the two-way test, and they
12 say, "its factual situation is not likely to be repeated."

13 THE COURT: Hold on a second. I think that's not --

14 MR. HURST: There was a heading special circumstances
15 triggering the two-way --

16 THE COURT: Yes. Okay. Go ahead.

17 MR. HURST: So *Berg* relies on *Braat*. There's very
18 little discussion in terms of what the facts were. The Federal
19 Circuit ended up following the two-way. This case said it "was
03:25 20 an unusual case; moreover its factual situation is not likely
21 to be repeated since the 1984 Act went into effect. Even
22 assuming that *Braat* retains some vitality," this case "is
23 nevertheless indistinguishable." Here is the point -- I don't
24 want to quibble. There's no question in the world they -- in
25 *Berg* you didn't have to file these in separate applications, so

1 therefore you're out of luck. But there's also discussion
2 about the additional requirements. If you go to the second
3 line of 1434.

4 THE COURT: Go ahead.

5 MR. HURST: "The court in *Braat*, however, emphasized
6 the more typical scenario in which, despite common inventive
7 entities, the two-way test applied," italics, "when a later
8 filed improvement patent issues before an earlier filed basic
9 invention." So that's the temporal requirement as well.

03:26 10 There's other quotes in the case that say that.

11 Here is one on the slide. "*Berg* should be viewed as
12 having taken a calculated risk by simultaneously filing two
13 separate applications. It might gain the advantage of a
14 quickly issued narrow patent and also the advantage of a
15 broader application which took longer to issue." So the
16 simultaneous filing was part of the decision. That's how the
17 Patent Office understood it.

18 Then I collected a few quotes. I don't know if it's
19 all of them, to tell you the truth. But on slide 26, where
03:27 20 this temporal requirement is repeated in *Berg*, one, two, three
21 different times, and there might be more. "When a later filed
22 improvement patent issues before an" --

23 THE COURT: What's the rationale of making a
24 distinction between two applications filed, say, a day apart
25 and two applications filed the same day?

1 MR. HURST: Because in order to get yourself
2 potentially to the two-way test, there has to be an unfairness
3 that was brought upon you by the Patent Office.

4 THE COURT: Solely by the Patent Office?

5 MR. HURST: Solely by the Patent Office, where you did
6 things in the right order, you sought your basic invention
7 patent first, and you later sought your improvement
8 application. And the Patent Office, despite you doing those
9 things in the right order, the Patent Office reverses them. If
03:28 10 there's no reversal either because you filed your improvement
11 patent first or you filed them at the same time without a
12 reversal, nobody could ever say it was the Patent Office's
13 fault. That's the reason. Here is a good quote from *Berg*.
14 And this is between 34 and 35.

15 "The two-way test exception" -- and this is where it
16 actually highlights both requirements, Your Honor. Here is
17 what they say. "The two-way test exception can only apply when
18 the application could not avoid separate filings," so that's
19 the separate filing requirement but then it goes, "and even
03:28 20 then," even then, "only if PTO controlled the rates of
21 prosecution to cause the later filed species claims to issue
22 before the claims for a genus in an earlier application." So
23 there's the temporal requirement, separate requirement, and it
24 does make logical sense, I believe.

25 That temporal requirement, I could tell you, every

1 case that talks about the two-way test talks about this
2 temporal requirement. I'm not saying they deal with it
3 directly, but they recite the test, the general standard in
4 this way, this temporal requirement, later-filed/earlier-filed.
5 Okay? So that's for the '195 patent that was issued on the
6 same day. The '272 patent, as we've discussed before, was
7 issued later in time. So you have to get -- if you reach that
8 patent, you have to get to the question of did the PTO -- was
9 the PTO solely responsible for the delay in causing the second-
03:29 10 filed application to issue prior to the first. And here, Your
11 Honor asked whether this could be a factual issue.

12 And there are cases, lots of cases out there that say
13 one-way versus two-way is a matter of law, but as you point
14 out, if there are factual issues to be decided underlying that
15 legal issue, then there could be an issue of material fact that
16 has to be resolved by a factfinder. But here there isn't
17 because it is undisputed that Janssen supplied at least a year
18 of the delay or more, at least a year of the delay or more.
19 They sought extensions of time, three extensions of time. They
03:30 20 declined to accept the patent when it was offered to them.
21 This extension -- we have a timeline here.

22 THE COURT: What number is that?

23 MR. HURST: This is slide 23 -- sorry, 28, Your Honor.

24 There was an Office action. The Patent Office issued
25 a decision on the pending claims in May of 1996. Janssen

1 sought a three-month extension to file a notice of appeal.

2 Then they didn't file a brief. Then they said, "Give me
3 another four months to respond to the Office action." The
4 result was a year of no prosecution from May of 1996 to when
5 they responded in May of 1997.

6 The problem here is every day, every day of delay by
7 Janssen, every day extends the life of the '471 patent beyond
8 the earlier-expiring indistinguishable patent, a patent it did
9 not cover. So that delay, when the PTO is not solely
03:31 10 responsible for it, meaning -- you know, there is a four-year
11 difference here. Janssen at least contributed to a year of it,
12 at least a year of it. The result was -- at least a year of
13 it. The result was that extends the life of the '471 patent.
14 It artificially extends the life of the patent that everybody
15 agrees does not claim a distinguishable invention from the
16 earlier-expiring '195 and '272 patents.

17 THE COURT: '272?

18 MR. HURST: '195 and '272. So that's why the rule is
19 so rarely applied. It's hard for anyone to show they weren't
03:32 20 responsible for any portion of the delay. Here it's no
21 dispute, at least a year. And literally every day that they
22 delayed the issuance of the '471 patent, every day artificially
23 extended the hurdle or obstacle to the public's ability to
24 practice the '195, '272 patents.

25 THE COURT: Okay.

1 MR. HURST: Now, what does Janssen propose? The way
2 they're arguing this is you should go through and count the
3 days that they contributed to the delay, count the days that
4 the PTO contributed, add and subtract and see -- well, what
5 happens if you subtracted my delays at Janssen, would the
6 patents still have issued in the same order if we just count
7 the PTO's delays. There's no case that does the analysis that
8 way. There is no case that does the analysis that way. And it
9 would defy the purpose of the doctrine. Because any delay that
03:33 10 Janssen contributed is part of artificially and therefore
11 unjustifiably extending the life of the '471 patent, which
12 artificially extends the lives of the '271, '195 patents.

13 You mentioned this case, the *Hubbell* case. It's a
14 similar circumstance. The argument was made, *Hubbell* said, I'm
15 entitled to two-way analysis because, on balance, it was really
16 the PTO's responsibility for the claims of the '685 patent
17 issuing before the present claims. And the Patent Office said,
18 Look, we understand, yes, we were partially responsible, but so
19 were you. You didn't have completely clean hands. We both
03:34 20 delayed here and there. And the court said that was enough.
21 It was a shared responsibility. The two-way test does not
22 apply. It's a really, really hard test to meet.

23 Another thing that Janssen says is you ought not
24 penalize us for routine extensions of time. That argument has
25 been tried and failed before the Patent Office. Here is one

1 example. In the *Fallaux* case, Dr. Fallaux says, Hey, listen.
2 I didn't mean nefarious intent. I just applied the rules that
3 I normally would apply when prosecuting, including getting
4 extensions of time. And the Federal Circuit said, That doesn't
5 matter. If you were partially responsible for the delay, you
6 cannot get access to the two-way test.

7 We haven't actually found a case -- and maybe I have
8 to reread the one you that you cited, Your Honor, but I don't
9 think I found a case where summary judgment was denied based on
03:35 10 factual issues over one-way versus two-way.

11 THE COURT: I don't think it was in Judge Bennett's
12 case, but I was just pointing out that this could be an issue
13 conceptually.

14 MR. HURST: Conceptually, I understand your point.
15 Your point is that even though it's an issue of law, there
16 might be underlying factual issues that need to be resolved. I
17 agree with that. That's the correct way to look at it. But I
18 think it would be hard to find such issues in a case where
19 there's a prosecution record. What happened happened, and
03:35 20 there's a record of it. I don't think anybody disputes, for
21 instance, our timeline.

22 Now, before I move on to the -- there's two ways to
23 get to the one-way test. The simultaneous filing dates --

24 THE COURT: One-way test?

25 MR. HURST: Yes. I would say that there's two

1 different ways to agree with us on the second issue. One is
2 the simultaneous filing dates between the '471 patent and the
3 '272. And even if you get past that, I think Janssen has to
4 agree that they were at least partially responsible for the
5 delay in the issuance date of the '471.

6 That brings me to my final topic, which is if the
7 two-way test applies, should the court consider the '471 patent
8 specification in the comparison. This issue we believe is
9 dispositive, too. So here's what normally happens for double
03:36 10 patenting. I think this is something you probably know, Your
11 Honor. You just compare a claim to a claim. You don't compare
12 the specifications. And that rule has been around for a long
13 time. So you don't read the spec. You just look for -- you
14 compare one claim against another claim.

15 THE COURT: You look at the spec to interpret the
16 meaning of the claim, we're going to be talking about this on
17 the '083.

18 MR. HURST: Yes, exactly. But you compare the claims.
19 But there's an exception. It just so happens to be a case that
03:37 20 I argued, and it's when there's a compound claim, when you
21 claim --

22 THE COURT: Where is --

23 MR. HURST: Slide 35. This is the *Sun Pharma* case.

24 THE COURT: Go ahead.

25 MR. HURST: Here is what *Sun Pharma* holds.

1 THE COURT: Actually, don't go ahead yet. I think I
2 have -- go ahead.

3 MR. HURST: I want to just read the holding, then I'll
4 explain what the rationale is. So *Sun Pharma* relied on two
5 earlier cases, *Geneva* and *Pfizer*, and held that they made clear
6 that, "Where a patent features a claim directed to a compound,
7 a court must consider the specification," must consider the
8 specification.

9 THE COURT: What page are you on?

03:38 10 MR. HURST: Page 35. Did I say 34?

11 THE COURT: 1835.

12 MR. HURST: You're looking at the case. 1387. My
13 apologies. I was giving you my deck slide.

14 THE COURT: Just a minute. All right. Here it is.
15 Okay.

16 MR. HURST: "Where a patent features a claim directed
17 to a compound, a court must consider the specification because
18 the disclosed uses of the compound affect the scope of the
19 claims for obviousness-type double patenting purposes."

03:39 20 Here is the rationale for that, Your Honor. It's
21 actually a constitutional issue. You don't actually have a
22 patentable invention unless it's useful. It has to be useful.
23 So if your claim just says, Here is my chemical compound,
24 without telling you how it's going to be used, it's not an
25 invention. So the rationale in all these cases is, Hey, look.

1 If you're just claiming this compound, you have to read the
2 spec to make it a complete invention. How will you use that
3 compound, what will you do with it to make it useful and
4 therefore a patentable invention under the Constitution of the
5 United States.

6 And so that's what they say. *Sun Pharma* again.
7 "Obviousness-type double patenting encompasses any use for a
8 compound that is disclosed in the specification of an earlier
9 patent claiming the compound and is later claimed as a method
03:40 10 of using that compound." So in *Sun Pharma*, the later claims,
11 later patents talked about methods of using the compound itself
12 called Gemzar to treat various cancers. And the argument from
13 Eli Lilly was, Hey, that's different from the compound itself.
14 The compound is one invention. Using that compound to treat
15 cancer is a new and different invention.

16 What the Federal Circuit said is no, when you read the
17 compound patent, the compound by itself doesn't do anything,
18 you have to tell me how you're going to use it. You read the
19 spec, and lo and behold, the spec said it used the compound to
03:41 20 treat the same cancers as the later patent. So that's how the
21 patents got invalidated here. And that's here as well. When
22 you go to the '471 patent, you look at this antibody claim, and
23 it tells you what you're going to do with it. The same things
24 that the '195 and '272 patents say. Use it to treat rheumatoid
25 arthritis. Use it to treat Crohn's disease.

1 THE COURT: This is from the spec?

2 MR. HURST: Yes. The '471 spec recites the very same
3 uses, very same uses as the '195 and '272 patents. This is
4 what you do with our antibody. You treat Crohn's, and you
5 treat RA, rheumatoid arthritis. It's as if, when you do the
6 comparison, Judge, if you look at slide 38, it's as if when
7 you're doing the claim comparison -- this is claim 6 of the
8 '471 patent -- you add language to it. I added red language to
9 it. "Wherein the antibody is used to treat rheumatoid
03:42 10 arthritis and Crohn's disease," when you do that and you
11 compare this claim, the '471 patent to the claims in '272 and
12 '195, same thing. So if you follow *Sun*, there's no
13 distinction.

14 So what is Janssen's argument here? They're saying
15 that you only follow *Sun*, only follow *Sun* -- this is their
16 quote, this exception that *Sun* created -- I guess a series of
17 cases, *Gemzar*, *Pfizer*, *Sun*.

18 THE COURT: What --

19 MR. HURST: Slide 39. I'm quoting from their
03:42 20 sur-reply.

21 THE COURT: Go ahead.

22 MR. HURST: So they're saying that the "exception"
23 that we're relying on "has only been applied in cases, unlike
24 this one, where the relevant claim recites a chemical compound
25 by its formula or chemical name without identifying any utility

1 for the compound. In those circumstances, only in those
2 circumstances, the specification must be consulted to ascertain
3 utility."

4 So what they're saying here is, if you look at slide
5 40, they're saying, Hey, look. When you look at the '471
6 slide, '471 claims, they call themselves anti-TNF antibodies,
7 so there's a utility there. Our antibody binds to TNF.
8 They're saying when you have that circumstance, you don't look
9 at the specification like you did in *Sun* and *Pfizer*. But
03:43 10 that's not true, Your Honor. This is the property of the
11 compound. The fact that the compound binds to TNF is not a use
12 for the compound. If you gave me this compound, it would in my
13 body bind TNF, but it would have no use. I do not have RA. I
14 do not have Crohn's. It's just a property of the compound.
15 That's all it is.

16 Bristol Myers, "From the standpoint of patent law, a
17 compound and all of its properties are inseparable; they are
18 one and the same thing." You don't have to look very far to
19 get confirmation of this, Your Honor. This is the *Centocor v.*
03:44 20 *Abbott* case from 2011. And it's literally -- it's at slide 41.
21 It's literally talking about the patents in the same chain --
22 in the same family as the '471.

23 Now, they're not talking about this issue, but they
24 are talking about the fact that binding to TNF is a property of
25 the compound. "The asserted claims constitute a wish list of

1 properties that a fully-human, therapeutic TNF antibody should
2 have, and that includes the ability to bind in the same place
3 as an equivalent mouse antibody." But they call it, the
4 anti-TNF binding, a property of the compound, and it makes
5 sense. It's not a use of the compound. It only becomes a use
6 of the compound when you use that property to accomplish
7 something, like treating a patient who has Crohn's or RA.

8 And that leads me to my final slide, Your Honor. So
9 just, for me, I mean, the easiest path in my mind is safe
03:45 10 harbor and the two patents that were filed, the two patents
11 that were filed in the same day. It seems like that's an easy
12 path to avoid any further complications beyond question two.
13 But obviously, we do believe that we prevail on each and every
14 one of those issues. Unless you have questions --

15 THE COURT: Not right now.

16 MR. HURST: Thank you, Your Honor.

17 THE COURT: We're going to take a ten-minute break.

18 We'll resume at five to 4:00. Court is in recess.

19 (Recess taken 3:45 p.m. to 4:00 p.m.)

03:59 20 THE COURT: Okay. You're up.

21 MR. DISKANT: Thank you, Judge. We have a collection
22 of slides as well. And I know it's been a long day. Always
23 excited to find a group of people here that want to talk about
24 double patenting, but I apologize if it bogs down. I'll try to
25 move through it reasonably expeditiously with the

1 understanding, as I'm sure Your Honor knows, that this is very
2 important.

3 THE COURT: Oh, I know. I was here all weekend.

4 MR. DISKANT: So let's talk about --

5 THE COURT: Or most of it.

6 MR. DISKANT: -- the so-called reexamination.

7 THE COURT: So we're going to make this Exhibit D.

8 Okay.

9 MR. DISKANT: Okay. I thought it would be useful to
04:00 10 begin just by taking a look at the patents themselves because,
11 while we've been talking about them, I think it helps the
12 analysis to take a look at them. And this was not prolonged.

13 Basically the '471 patent, as Your Honor has said many
14 times, there are several asserted claims, but claim one is
15 exemplary. It claims a chimeric antibody that's capable of
16 binding the TNF-a, and it's selected from a group of
17 antibodies. So it is a genus claim, a collection of
18 antibodies. So you would call it a compound patent or a
19 generic patent.

04:01 20 The '195 patent is a method of treating rheumatoid
21 arthritis by administering in particular anti-TNF antibody cA2.
22 And the one -- and this is the reference claim, so while there
23 are more than one claim in the patent, this double patenting
24 analysis is entirely about claim 6 of the '195 patent,
25 sometimes called the asserted claim -- excuse me -- sometimes

1 called the reference claim. And then in the '272 patent, it's
2 a method of treating Crohn's disease by administering again
3 anti-TNF antibody cA2.

4 Now, the three patents were all filed in 1994. Two of
5 them, the '471 and the '272, were filed on February 4, and the
6 '195 was filed in October. Now you see the reverse of what we
7 were talking about this morning in *Gilead*. The '195 and '272
8 issued first. So under classic double patenting analysis, the
9 question is whether the issuance of the later patent, the '471,
04:03 10 improperly extended the term of those earlier-filed patents.
11 That's classic double patenting analysis. That has nothing to
12 do with *Gilead*. And these are all pre-URAA patents. They also
13 share the same priority date. And as I just described, they
14 have three different issue dates.

15 So here is the summary of our argument. First, we
16 contend the safe harbor protects the '471 patent from double
17 patenting.

18 THE COURT: Hold on just a second.

19 MR. DISKANT: Sure.

04:03 20 THE COURT: What slide are you on?

21 MR. DISKANT: What I'm up to right now is slide 8.

22 THE COURT: Okay.

23 MR. DISKANT: So first we have a safe harbor argument,
24 and then secondly we say, in any event, there's no double
25 patenting under the two-way test. And either one of those is

1 sufficient to protect our patent from double patenting. We
2 then say, or relatedly we say there are many fact disputes on
3 both of these issues which preclude summary judgment. And
4 lastly, I know Your Honor has denied the stay. I'm not going
5 to belabor this. We think as a matter of judicial prudence you
6 should take a pass.

7 And there are two components of that. One is if you
8 choose to rule against us on the *Gilead* issue, we don't think
9 it's necessary to address this. And secondly, on the very
04:04 10 point that you had colloquy with counsel about what happens if
11 you rule against us on this reexam issue and what happens in
12 the reexam, he quoted me accurately but incompletely, which is
13 to say that if Your Honor rules against us on the reexam and
14 Your Honor's ruling is affirmed by the Federal Circuit on
15 appeal, then --

16 THE COURT: I think I said that today.

17 MR. DISKANT: Oh, that's correct. That's the right
18 way to think about it. I think as a practical matter -- well,
19 who knows what's going to happen? But there is the reexam.
04:05 20 It's going to have oral argument at some point. It will be
21 decided at some point. Maybe all these cases will be in the
22 Federal Circuit at the same time. We have no way of knowing.
23 But yes, the reexam comes to a close -- is closed out only if
24 the Federal Circuit affirms an invalidity ruling.

25 Okay. So the safe harbor. Now, there are three

1 cases. We'll talk about the three cases. And the essence of
2 the argument that I'd like to make to you is the three cases do
3 not stand for a per se rule that a safe harbor is unavailable
4 unless it's literally filed as a divisional. There is room in
5 that body of case law for equity to be considered and for the
6 facts to be considered, and so I'd like to spend some time on
7 the facts and then address the case law on why I think they
8 leave room for Your Honor to consider the facts.

9 So we start with, you know, how did this all come
04:06 10 about. The restriction requirement. The restriction
11 requirement, basically it's in 121. If the director believes
12 there are two or more independent inventions in an application,
13 he may order them separated. And that's not a rule of patent
14 law. There's nothing that says you can't have them all
15 together. But for administrative convenience, the director may
16 order them separated.

17 Before the safe harbor, there was a gotcha quality to
18 this. And the gotcha quality was, during prosecution, you're
19 in the Patent Office, the Patent Office says, Hey, your two
04:07 20 inventions are patentably distinct, separate them. You filed a
21 single application for a widget and using the widget. And the
22 Patent Office says, Those are two inventions, separate them.
23 Okay. You separate them. Now you've taken your single
24 application and you've turned it into two applications, one for
25 the widget and one for the method of using the widget. Then

1 you get patents. Then you start to enforce them in litigation.
2 And your adversary says, essentially, the Patent Office was
3 wrong. Those aren't patentably distinct inventions. They're
4 obvious variants. You should have filed one application, but
5 since you filed two, one of those is invalid for double
6 patenting.

7 That is unfair. That was recognized to be unfair for
8 many, many years. And as the Federal Circuit said in *Pfizer*,
9 the inequity of this practice was well known by 1952 and that's
04:08 10 what led to the safe harbor, eliminating that gotcha. If you
11 file a single application and you're forced to separate it,
12 you're not going to lose your patents as a result. The purpose
13 was to eliminate the inequity and allow applicants to
14 reasonably rely on restriction requirements. I emphasize that
15 because at the heart of this doctrine, it's not technicalities.
16 It's equity. Is what happened fair?

17 THE COURT: Well, let's see. What year did you file
18 the different --

19 MR. DISKANT: '94.

04:09 20 THE COURT: '94. That was before --

21 MR. DISKANT: All of these cases.

22 THE COURT: -- before the cases interpreting the safe
23 harbor?

24 MR. DISKANT: That's right. Long before.

25 THE COURT: But you could have filed divisional

1 applications, all divisional applications, right?

2 MR. DISKANT: Yes.

3 THE COURT: And you chose instead to file for the
4 '471, a continuation-in-part.

5 MR. DISKANT: That's right.

6 THE COURT: So why is it inequitable to hold you to
7 what the law now says are the consequences of that decision?

8 MR. DISKANT: Well, I'm going to tell you that, but
9 actually that's a very good point, because Celltrion somewhat
04:09 10 misrepresents our point. I know when the law is declared it
11 has retroactive effect. I'm not suggesting that if there's
12 black letter law that you can't do X, then the fact that I made
13 a mistake 20 years ago just doesn't matter. I get that. We're
14 not arguing that.

15 What we are arguing is the law is not so black letter,
16 it's not so rigid, and the law leaves room for considering the
17 circumstances of the matter and the equities. And I'd like to
18 explain to you why we think it's equitable to do what we did.

19 THE COURT: First, I think you need to explain to me
04:10 20 why I have that discretion, because the language that was
21 decided from, I think, the trilogy of cases seems unequivocal.

22 MR. DISKANT: Okay. I can jump ahead. I'll do that
23 and then I'll come back to the facts if you're interested.

24 THE COURT: I'm sorry. You can go to the facts if you
25 want, but I thought you were going to start talking about the

1 equities.

2 MR. DISKANT: I am, but I'm going to do that through
3 the facts and I'm going to talk about why the cases don't
4 preclude that.

5 THE COURT: You do it your way. You do it your way.

6 MR. DISKANT: Okay. 13. In any event, "The purpose
7 of 121," says the Federal Circuit, "assures that technicalities
8 of restriction practice are not elevated to create a potential
9 taint on the validity of patents." As the reports explained,
04:11 10 it means --

11 THE COURT: I'm sorry. Which number is this?

12 MR. DISKANT: I'm now on slide 13, Judge. This is
13 quoting from *Applied Materials*. The consequence of Section 121
14 is that "neither of the resulting patents can be held invalid
15 merely because they were divided into several patents." That's
16 the equities that led to 121. And I have here the text of 121
17 just so we can see it. Your Honor has probably studied it, but
18 let me just focus on the first sentence.

19 "If two or more independent and distinct inventions
04:11 20 are claimed in one application, the director may require the
21 application to be restricted to one of the inventions," and
22 then it continues, and this is the safe harbor, "A patent
23 issuing on an application with respect to which a requirement
24 for restriction has been made," and those will be the '195 and
25 '272, "shall not be used as a reference in the courts against a

1 divisional application or against the original application or
2 any patent issued on either of them."

3 THE COURT: Can we go back to 14?

4 MR. DISKANT: Yes.

5 THE COURT: Because you read the highlighted part, but
6 the next bullet says, "If the other invention is made the
7 subject of a divisional application, which complies with
8 certain requirements, it's entitled to the benefit of the
9 earlier filing date." So it says "divisional application."

04:12 10 MR. DISKANT: It does. It says it also in the
11 sentence that I read to you, which is I think the applicable
12 sentence. We're not talking about a filing date issue. We're
13 talking here in the highlighted portion of the second page, "It
14 shall not be used as a reference in the courts against a
15 divisional application or a resulting patent." That's the
16 language that creates the issue in this case.

17 THE COURT: Did this statute exist in 1994?

18 MR. DISKANT: Yes. It existed in 1952.

19 So how should an applicant proceed knowing that there
04:13 20 is a safe harbor out there and not knowing what to do? The
21 *Berg* case actually has very clear advice. "If a potential
22 applicant is unsure whether it has more than one patentably
23 distinct set of claims, the PTO advises that it file all the
24 claims as one application. Then, if the PTO determines that
25 more than one distinct invention was claimed, then Section 121

1 authorizes the commissioner to restrict the claims to a single
2 invention, and then because they filed the related claims in
3 one application, the applicant is protected from an
4 obviousness-type double patenting rejection if the PTO later
5 determines that the applicant is submitting claims to more than
6 one patentable invention."

7 Essentially what the *Berg* court is saying is to do
8 exactly what Janssen in fact did. Janssen filed a single
9 application. Now I'm up to slide 18. Janssen filed a single
04:14 10 application for its infliximab invention. The PTO issued a
11 restriction requirement saying that there were five groups of
12 inventions. Janssen continued prosecution in one group in one
13 patent, filed separate applications in the remaining groups,
14 including the '471, in the belief that it was entitled to the
15 safe harbor, and the PTO confirmed during prosecution that it
16 was entitled to the safe harbor.

17 THE COURT: Hold on just one second.

18 MR. DISKANT: Sure.

19 THE COURT: So this is page?

04:15 20 MR. DISKANT: Now I'm on 18. Sorry. You're back on
21 *Berg*.

22 THE COURT: I'm on 16.

23 MR. DISKANT: *Berg*, sure.

24 THE COURT: I'm trying to find this in context. I see
25 at the top of page 1436 there's discussion of one or more

1 divisional applications.

2 MR. DISKANT: Wait a second. Here we go. Sorry. My
3 copy is hard to find the page numbers on.

4 THE COURT: Do you know where this language is?

5 MR. DISKANT: Let me find it. I'm on 1435 under the
6 section that says C, "The options available in *Berg* were
7 reasonable." It begins there. "A potential applicant is
8 unsure."

9 THE COURT: Okay. Your slide says that's on 1436.

04:16 10 MR. DISKANT: I'm so sorry, Judge. I apologize.

11 THE COURT: 1436 says in the same paragraph on page
12 1436, it says, "If claims are so restricted, one or more
13 divisional applications can be filed."

14 MR. DISKANT: Then it says, "When such a divisional
15 application is filed, the PTO is prohibited from using the
16 claims of the patent issuing on the application and as a
17 reference against the claims of any divisional application,"
18 and it continues.

19 THE COURT: Okay.

04:17 20 MR. DISKANT: I'm not saying the words aren't there,
21 Judge. I know the words are there. The question is what's the
22 -- well, the question from our perspective is what are the
23 facts of what we did, and is there room under the case law to
24 deem -- "deem" is the word I'd like to use, because it's the
25 word the *Amgen* court uses. Are there reasons under the case

1 law to deem the CIP that we in fact filed is a divisional.
2 That's our argument, and that's what it is.

3 So anyway, so let me go to slide 20 now, going through
4 what happened. So in the PTO, this is October '93, the PTO
5 says, "Because these inventions are distinct, restriction for
6 examination purposes is proper." That is the restriction
7 requirement.

8 THE COURT: Go ahead.

9 MR. DISKANT: Sorry. So the restriction requirement
04:19 10 is in October '93. And then Janssen separates the applications
11 as directed by the PTO. The '471 is group one and the other
12 two come from group four.

13 So then we file -- in October '94 we file the '471 as
14 a continuation-in-part. And we explained to the PTO that we're
15 filing the preliminary amendment pursuant to the restriction
16 requirement. And as we'll see in a moment, the reason it's a
17 CIP is because it adds some new information, although it's
18 unrelated to the claims that we're seeking.

19 Now, a couple of years later, the PTO rejects the '471
04:19 20 for double patenting. That's what we're looking at on slide
21 23. And that application '799 is what becomes the '195 patent.
22 So essentially it's the same argument that Celltrion's making
23 here. There's a double patenting problem with the '471 patent
24 over the '195 patent. And Janssen responds by saying, among
25 other things, that Section 121 precludes obviousness-type

1 double patenting; see out restriction requirement. That's the
2 defense we're making right now. That's what we argued to the
3 PTO in May of 1997. And the PTO then withdrew the double
4 patenting objection in light of our claim to the safe harbor
5 and it never asserted it again throughout prosecution.

6 Now, what's this happening, what's happening now? I
7 would say what's happening now is Celltrion is exploiting the
8 same inequity that led to the safe harbor. We were told by the
9 PTO to separate these because they're distinct, and now
04:21 10 Celltrion's arguing, Well, they're not really distinct so you
11 lose. And that's the equity point. That is the equity point.

12 Now, the question then is does the CIP matter. And of
13 course that's what the case law talks about and what I'd like
14 to persuade Your Honor to view with an open mind. So first --

15 THE COURT: I always deal with it with an open mind.

16 MR. DISKANT: I'm sorry.

17 THE COURT: I always deal with it with an open mind.
18 When it comes to patent cases, it's with an empty mind, and you
19 need to fill it up.

04:21 20 (Laughter)

21 MR. DISKANT: I'm sure your mind and mine are both
22 quite full by now. In any event, I say that just in light of
23 your preliminary observations that I'd like you consider --

24 THE COURT: That's why I said they're tentative views,
25 and with regard to this motion they're particularly tentative.

1 MR. DISKANT: As Your Honor knows, there are fact
2 questions and there are law questions. And what makes this
3 different so far as I can tell from the other cases is they're
4 fact disputes supported by sworn testimony from declarants. We
5 have Carolyn Elmore.

6 THE COURT: What slide is that?

7 MR. DISKANT: Now I'm up to slide 30.

8 THE COURT: Go ahead.

9 MR. DISKANT: Carolyn Elmore was a U.S. patent
04:22 10 examiner for eight years and then she went into private
11 practice. And she was the principal patent prosecutor for the
12 '471 patent. And she has put in a declaration explaining to
13 you what happened. And Steven Kunin is an expert witness. He
14 was the deputy commissioner for patent examiner policy during
15 all these years and knows in more detail probably than anyone
16 living exactly what many Patent Office policies and procedures
17 were for examining patents like this.

18 So counsel mentioned the different kinds of
19 applications, continuation, divisional and
04:23 20 continuation-in-part. As germane here, these are the
21 definitions -- now on I'm slide 32 -- the definitions from
22 1994.

23 The essential difference between the divisional and
24 the CIP or continuation-in-part is the continuation-in-part has
25 added matter that's not disclosed previously. Now, there's a

1 lot to that concept and because they're two completely
2 different directions that can head in. I would say most
3 commonly, new matter supports new claims. My original
4 application says I invented the widget. Then my
5 continuation-in-part says I've discovered the widget can be
6 used for A, B and C, and I want a patent claim to using the
7 widget for A, B and C. That's, I would say, the most common
8 use of new matter.

9 But you can have new material in a patent that's just
04:24 10 there that's not part of any claims. It's not there to note
11 claims that limit the public's ability to use your invention.
12 But rather you add matter that informs the public of more
13 information about your invention without restricting their
14 ability. That's what we have. And that's, to me, one of the
15 single most relevant facts in thinking about the equities here.

16 So here is, from Ms. Elmore's declaration -- now we're
17 on 33. "At the time the application was filed, it was not
18 unusual for an applicant to add material as it became
19 available." We were doing ongoing research, and we added
04:24 20 material about our research. And as soon as you do that, you
21 cannot call it a divisional. You have to call it a CIP, even
22 though it makes no difference in terms of the claims you're
23 looking for. Mr. Kunin --

24 THE COURT: You define the claims, but it may
25 strengthen your argument that the patent should be issued.

1 MR. DISKANT: It becomes a fact question, Judge. The
2 facts that we've alleged, and frankly the facts that we've
3 proved to the Patent Office in the reexam are that this new
4 matter made no difference. So it's a disputed fact issue, but
5 that is our declarant's sworn contention, and it's true. We've
6 proved it's true.

7 Mr. Kunin says, "The designation as a CIP was required
8 under the specific naming nomenclature because additional
9 material had been added." So here we have Section 121 enacted
04:26 10 to be fair, not to tangle people up in the niceties of patent
11 procedure, but to be fair. We add new material. You can't
12 call it a divisional because there's new material in there, but
13 it's irrelevant to the claims.

14 THE COURT: But you -- well, "but it's irrelevant to
15 the claims" is I don't think something I can accept on this
16 record.

17 MR. DISKANT: No, you can't.

18 THE COURT: It just seems to me that, like, if *Amgen*
19 means what it says, continuation-in-part is not a divisional,
04:26 20 then, you know, you have a choice. You could have filed a
21 divisional and not added any information, or you could have
22 made it a continuation-in-part, adding information for some
23 reason, unknown, I would say, for present purposes, and the
24 question is whether I have discretion to -- whether you have to
25 be held to the consequences of that decision or whether there's

1 some discretion to deem CIP a divisional.

2 MR. DISKANT: That's exactly the issue, Judge. That's
3 exactly the issue. We agree that if Your Honor's view of the
4 case law is there's no discretion, then we lose.

5 THE COURT: What about the statement at *Amgen* at 1353?
6 "We are persuaded by the reasoning in *Pfizer* that the 121 safe
7 harbor provision does not protect continuation applications for
8 patents descending from only continuation applications. The
9 statute on its face applies only to divisional applications,
04:28 10 and a continuation application like the continuation-in-part
11 application is not a divisional application."

12 MR. DISKANT: Well, then you have to read that in
13 light of the paragraph on -- I think -- I'm sorry. I'm trying
14 to find the page number, Your Honor. The paragraph begins,
15 "Furthermore." It's on 1354. Is that what you were on, Judge?

16 THE COURT: No. I was on 1353.

17 MR. DISKANT: So the next page, 1354, the paragraph
18 says, "Furthermore, Amgen has not presented us with any
19 persuasive reason as to why we should deem the '178 and '179
04:28 20 continuation applications divisional applications for purposes
21 of Section 121." So I'm going to discuss the facts in just a
22 second. But to me what that is saying is the court is open to
23 the argument that on the right set of facts, it will deem an --

24 THE COURT: No. I'm a little concerned that if I
25 accept that argument the Federal Circuit will say, "I think

1 Judge Wolf can't read anymore." It says, "Amgen argues that
2 because the '178 and '179 continuation applications could have
3 been filed as divisional applications, we should treat them as
4 such for the purpose of Section 121."

5 MR. DISKANT: Mm-hmm.

6 THE COURT: "While this argument convinced the
7 District Court to regard the '178 and '179 continuation
8 applications as divisional applications, we are not likewise
9 convinced. We decline to construe 'divisional application' in
04:30 10 Section 121 to encompass Amgen's properly filed, properly
11 designated continuation applications."

12 How is this case different than that? It sounds to me
13 like you're asking me to do what the Federal Circuit said it
14 wouldn't do in *Amgen*.

15 MR. DISKANT: I think not. The reason I think is not
16 is because, in *Amgen*, this is all they had, which is to say the
17 facts were, just as the court says, check the continuation box,
18 et cetera. The facts are what are recited here. What is
19 missing in *Amgen* is there's no proof in the prosecution history
04:30 20 that the continuation was filed as the result of a restriction
21 requirement, whereas in our prosecution we said so explicitly.
22 There's nothing in the prosecution history that says we believe
23 we were entitled to the safe harbor, and ours says so
24 explicitly. In *Amgen*--

25 THE COURT: In the prosecution history?

1 MR. DISKANT: Yeah. Our prosecution history
2 explicitly says we believe we're entitled to the safe harbor.

3 THE COURT: You said that in 1994?

4 MR. DISKANT: Yeah. I just showed it to you. I'll go
5 back.

6 Right here, slide 24. This is 1997. In 1997, the PTO
7 rejected our application for obviousness-type double patenting
8 over the -- patent, exactly the argument these folks are making
9 right now. We said no, we're protected by 121.

04:31 10 THE COURT: What did the Patent Office say then?

11 MR. DISKANT: It said, "The following rejections are
12 withdrawn, obviousness-type double patenting." And they didn't
13 mention it again. So that's what happened. And Ms. Elmore and
14 Mr. Kunin says we relied on that. So these facts --

15 THE COURT: And Janssen relied on it.

16 MR. DISKANT: Yeah, Janssen relied on it. So these
17 facts are, to me, you know, unusual, explicit, and *Amgen*
18 doesn't have anything like that. So, you know, I think, Judge
19 Wolf, you can read this paragraph very well, and it says
04:32 20 exactly what you say it says. But to me, if I had to focus on
21 what words I thought were important in this paragraph, I would
22 focus on the first sentence, "Amgen has not presented us with
23 any persuasive reason to deem it a divisional," and the last
24 sentence, "We decline to construe 'divisional application' in
25 121 to encompass Amgen's continuation application."

1 THE COURT: But they don't say, "In the circumstances
2 of this case we don't." It seems to me more categorical.

3 MR. DISKANT: If Your Honor wants to read it that way,
4 I agree we lose. I believe, in reading these cases, that there
5 is room in the case law for a factual record to be made that is
6 different than the factual record in the three cases and that
7 is persuasive that this is fair under the circumstances to deem
8 our application a divisional for purposes of the safe harbor.

9 THE COURT: Is there any case in which the Federal
04:33 10 Circuit has deemed a continuation or continuation-in-part a
11 divisional for the purposes of the safe harbor?

12 MR. DISKANT: These are the three cases, Judge.

13 THE COURT: There's no case where the Federal Circuit
14 has reached that result?

15 MR. DISKANT: No. So to go back to the story,
16 Mr. Kunin continues that, "In accordance with practice at the
17 time, the fact that the application was denominated as CIP did
18 not necessarily take it outside of the safe harbor."

19 THE COURT: That's not something -- that's a question
04:34 20 of law. That's not something any expert would be permitted to
21 testify on in court.

22 MR. DISKANT: I'll tell you why I disagree.

23 THE COURT: He can testify to custom and practice if
24 we're having a trial, but he's not going to tell the jury that.

25 MR. DISKANT: Well, custom and practice is I think

1 what he was referring to. I'm fine either way. To me, the
2 relevance of this is if there's room for discretion -- and if
3 there's no room for discretion, it doesn't matter what the
4 practice was. But if there's room for discretion, then it
5 does. And that's the purpose of Mr. Kunin's declaration. And
6 he continues on slide 35: "It was accepted practice at the PTO
7 to allow CIPs safe harbor protection if claim consonance was
8 maintained consistent with the restriction requirement." Claim
9 consonance is an issue that's not in the case. They don't
04:35 10 challenge that. So basically this is saying it was accepted
11 practice to allow this to be a safe harbor on our facts.

12 THE COURT: Excuse me. You have somebody talking over
13 your right shoulder. It's distracting.

14 MR. DISKANT: I'm sorry, Judge.

15 In any event, Ms. Elmore, the patent prosecutor, more
16 or less says the same thing. "At the time it was being
17 prosecuted, the fact that additional material was included and
18 thus it had to be identified as a CIP didn't take it
19 necessarily outside the safe harbor." And Kunin reviews the
04:35 20 MPEP at the time, and his understanding of the MPEP at the time
21 was again so long as consonance is maintained and the claims
22 were filed as the result of a restriction requirement, the safe
23 harbor applies, even if it's designated as a CIP based on a
24 naming nomenclature. The naming nomenclature is mostly a rule
25 of convenience. It's just what bucket to put it in as

1 Mr. Elmore -- excuse me -- as Mr. Kunin understood the facts
2 then.

3 He also reports that the new material that was added
4 didn't benefit us because it wasn't needed to support the
5 antibody claims, which the PTO has also found. And Ms. Elmore
6 explains that amending -- that had the PTO rejected our
7 statement that the safe harbor applies and says, No, this has
8 to be a divisional, it would have been easy to make it a
9 divisional. Just yank out the new material which was
04:37 10 unnecessary. Mr. Kunin agrees. The '093 application could
11 have been amended to delete the new material, making it a
12 divisional.

13 And then this Office action I just took you through in
14 which we expressly cited the safe harbor and said we were
15 relying upon it, 41 and 42, Ms. Elmore says she relied on that
16 in her patent prosecution decisions at a time when it could
17 have been turned into a divisional without consequence. And
18 Mr. Kunin says, "If the PTO required that it be denominated
19 divisional, it would not have withdrawn the objection."

04:37 20 THE COURT: I'm sorry. Say that again.

21 MR. DISKANT: If the PTO required that it be in the
22 form of a divisional, it would not have withdrawn the
23 obviousness-type double patenting rejection. That is what he
24 concludes from the prosecution history, namely that Janssen was
25 reasonable in relying upon the PTO action in believing it was

1 entitled to the safe harbor. So Mr. Kunin's view is that the
2 patent is a divisional insofar as its claims are concerned and
3 it's a CIP insofar as it has new matter in it. That's the
4 essence of our argument, that it's appropriate on our facts
5 proven through sworn testimony to deem --

6 THE COURT: Well, I doubt I could find they're proven
7 now. I might find at best -- I might find a genuine disputed
8 fact, and then I have to decide whether it's material. And if
9 I have no discretion, because *Amgen* means what it seems to say,
04:39 10 then the dispute is not material.

11 MR. DISKANT: I understand that, Judge. I'm not
12 asking you to rule in our favor. We didn't cross-move for
13 summary judgment.

14 THE COURT: Okay. We understand each other.

15 MR. DISKANT: We understand. Anyway, all I'm saying
16 is all these facts are disputed. These are on 46. And if they
17 don't matter, well, then they don't matter. To us, this makes
18 this case very different than any of the three cases. And then
19 the question is do the three cases leave room for equity, or
04:39 20 are we -- is it just going to be a per se rule, you lose.

21 So let me talk about the three cases. The first of
22 them is *Pfizer*. *Pfizer* was a CIP. Now I'm on slide 49. And
23 you can't tell this easily from the opinion, but if you go
24 through the cases and get to the *Searle* opinion and work
25 backwards, you learn that the CIP in *Pfizer* was almost entirely

1 based on new matter. We've crossed out all the claims that are
2 based on new matter, and I think there are about four that are
3 not.

4 So the *Pfizer* court had in front of it this CIP, a
5 classic CIP in which many, and in this case almost all of the
6 claims were in fact based on new matter. And so what did it
7 say? First, it repeated what I started with earlier, which is
8 there was this unfair gotcha in the law before the safe harbor
9 in which the PTO would say the claims were patentably distinct,
04:41 10 and then in litigation they would say no, they're not, and it
11 just didn't seem fair when you separated the claims only
12 because of the restriction requirement. And the *Pfizer* court
13 says that was inequitable, and it says the purpose of the safe
14 harbor is to allow applicants to reasonably rely on restriction
15 requirements. And I think at the very core that's what we say
16 we did. We got a restriction requirement. We relied on it.
17 We added some new matter that was not material to the claims,
18 which at the time seemed innocuous enough. We discussed the
19 safe harbor entitlement with the PTO. The PTO withdrew a
04:41 20 double patenting objection, and so this was -- we feel like
21 we're in a gotcha.

22 I mean, that's basically how, you know, my client
23 views what happened. What it did was reasonable under the
24 circumstances, at the time, in compliance with direction, and
25 now it's being faced with the argument that these claims that

1 were separated only because the PTO told them to separate them
2 are invalid.

3 So the *Pfizer* court talks about why the section is
4 limited to divisionals as best it can speculate from the
5 Congressional record. And it says, "If the section had
6 included CIPs, which by definition contain new matter, the
7 section might be read as providing an earlier priority date
8 even as to the new matter" -- I'm on slide 51, Judge --
9 "contrary to the usual rule that the new matter is not entitled
04:42 10 to the priority date of the original application," and to me
11 this is the key, "there was no possible reason for protecting
12 the new matter from double patenting rejections."

13 Well, I agree with that. There's no reason to protect
14 new matter from double patenting rejections. But we don't have
15 any new matter in our claims. Our claims aren't based on new
16 matter.

17 THE COURT: Wait. This is 1361.

18 MR. DISKANT: Yes, sir, 1361 on *Pfizer*. It's the big
19 paragraph that begins, "There's no suggestion in the
04:43 20 legislative history."

21 THE COURT: Which paragraph is it in? "There was no
22 possible reason for protecting the" --

23 MR. DISKANT: It's the last sentence of the paragraph.
24 The paragraph begins, "There's no suggestion, however, in the
25 legislative history."

1 THE COURT: All right. Yeah, that goes over to 1362.

2 Just a second, please.

3 MR. DISKANT: Sure.

4 THE COURT: But there was new matter, that's what made
5 it a continuation-in-part. There may not have been new claims.

6 MR. DISKANT: Right.

7 THE COURT: But there was new matter, wasn't there?

8 MR. DISKANT: There was new matter, but what this is
9 talking about, there's no possible reason for protecting the
04:44 10 new matter from double patenting rejections. To my reading at
11 least it's talking about claims based on new matter. It's not
12 saying that *in hoc verba*, but when you're talking about
13 priority dates and rejections, you're talking about claims.

14 THE COURT: Just a second.

15 What about the new next paragraph? It says, "The
16 difference between divisional applications and CIPs moreover
17 was well known at the time that Congress enacted the 1952
18 Patent Act. The Manual of Patent Examining Procedure in use at
19 the time included definitions of the different types of
04:45 20 applications. A divisional was defined as a later application
21 for a distinct or independent invention carved out of a pending
22 application and disclosing and claiming" -- disclosing and
23 claiming -- "nothing not disclosed in the earlier or parent
24 application. A CIP was defined as an application filed during
25 the lifetime of an earlier application by the same applicant

1 repeating some substantial portion of all of the earlier
2 application and adding matter not disclosed in said earlier
3 case."

4 So "matter," this seems to say to me, includes either
5 new claims or new disclosed information about the preexisting
6 claims.

7 MR. DISKANT: Well, new matter is anything that's not
8 disclosed. It certainly is intended to be broad, and these are
9 the definitions. And those are the ones I quoted to you
04:46 10 earlier. However, Mr. Kunin reads other provisions of the MPEP
11 as allowing CIPs to be entitled to the safe harbor. This is
12 silent on the safe harbor. This is just definitional.

13 THE COURT: I don't think it's silent on the safe
14 harbor. They're talking about the safe harbor.

15 MR. DISKANT: No. These are just the definitions --

16 THE COURT: No. It's in the paragraph that says
17 there's no suggestion that Section 21 was directed at anything
18 but divisional applications.

19 MR. DISKANT: Oh, yeah. I'm sorry. I was following
04:47 20 you. I agree with you this paragraph that says there's no
21 suggestion is talking about the safe harbor. I'm saying the
22 next paragraph you were reading to me, the definitions, the
23 definitions are standalone. They're not tied to the safe
24 harbor in the definitional sections of the MPEP.

25 But stay with *Pfizer* with me because I think it's

1 useful. In the next paragraph in *Pfizer*, it says "*Pfizer's*
2 only claimed authority are three cases in which the court may
3 have assumed that 121 did apply to CIPs." And, you know,
4 essentially they go through them and say, Well, it wasn't
5 decided. They're not denying it may have assumed that, but
6 it's not decisional, so we can keep on --

7 THE COURT: Yeah. But the holding -- the paragraph
8 after that, "We conclude that the protection afforded by
9 Section 121 to applications or patents issued therefrom filed
04:48 10 as a result of a restriction requirement is limited to
11 divisional applications." That seems pretty clear, unqualified
12 and applicable.

13 MR. DISKANT: Your Honor, if you read it that way, we
14 lose.

15 THE COURT: Then I think -- it's ten minutes of 5:00.
16 I think you should move to the next argument.

17 MR. DISKANT: Okay. Before I move on, let me just say
18 one more thing, which is this, which is I'd respectfully
19 suggest to Your Honor that if you think you should rule against
04:49 20 us on this, it will be far better to do so on a well-developed
21 factual record in which we're able to prove all of these
22 things. That's my suggestion, which you're obviously free to
23 reject.

24 Turning to the two-way test --

25 THE COURT: I wouldn't let an expert tell me what the

1 law is. *Marx v. Diners Club*, there's a whole line of cases.
2 They can talk about custom and practice if it's relevant to an
3 issue like was somebody's conduct reasonable. But I'm not
4 going to take expert evidence, let a jury hear expert evidence
5 or I wouldn't hear expert evidence on what the law is, unless
6 you were talking about foreign law or something.

7 MR. DISKANT: I agree with that, Judge. Our evidence
8 would be that the --

9 THE COURT: I understand. I think I understand.

04:50 10 Anyway, why don't you move to the other -- why you win anyway
11 even if you're not protected by the safe harbor.

12 MR. DISKANT: Exactly, why we win anyway. We win
13 anyway under the two-way test.

14 THE COURT: You acknowledge you would fail the one-way
15 test?

16 MR. DISKANT: To be most precise, we are not
17 challenging that in this proceeding. Yes.

18 In any event, "The two-way test must be used" -- this
19 is this court, not Your Honor, I think it's Judge Young -- I'm
04:50 20 now on slide 66 -- "if the applicant could not have filed both
21 claims together in the earlier-filed application and the
22 applicant did not cause the later-filed claim to issue first by
23 delaying examination of the earlier-filed claim during the
24 period when both applications were pending."

25 So their first argument, which counsel spent some time

1 on this afternoon, is the fact that the '471 and the '272 were
2 filed on exactly the same day rather than a day apart. And I
3 think Your Honor wanted to know why that small difference could
4 possibly matter.

5 In our view, it doesn't, and there's no law that says
6 that it does. They rely on *Berg*, and I think Your Honor knows
7 *Berg*, but *Berg* holds that "simultaneously filed applications
8 are ineligible when they could have been filed in a single
9 application." And it says that loud and clear and repeatedly.
04:51 10 "Because *Berg* could have filed the claims of its separate
11 application in a single application and it simply chose to file
12 two applications despite nearly identical disclosures, *Berg* is
13 not entitled to the two-way test."

14 THE COURT: What slide is that?

15 MR. DISKANT: That's slide 68. That's from *Berg* 1434.
16 "The two-way exception can only apply when the applicant could
17 not avoid separate filings."

18 THE COURT: So here you couldn't avoid separate
19 filings because you were told by the PTO you had to separate
04:52 20 them. So you get that far.

21 MR. DISKANT: We get that far. And indeed, the true
22 first filing had everything in it. And if the PTO hadn't
23 issued the restriction requirement, you know, presumably it
24 would have issued as a patent one day and we wouldn't be here.

25 So I think that, you know, having filed a single

1 application and being told to separate them, it is not a
2 decisional consequence that we filed two of those on one day
3 and another a day or so -- actually a couple of months later.
4 And there's no case that says that. Because we did just what
5 Berg said to do, which we looked at earlier. If we're unsure
6 what to do, we should file them all together and let the PTO
7 tell us what to do. That's what we did.

8 So we have this restriction requirement. And from our
9 perspective, by complying with the restrictional requirement we
04:53 10 should have been entitled to the safe harbor. You never get to
11 the two-way test. But, you know, I think we're squarely what
12 Berg is talking about, "Two-way exception can only apply when
13 the applicant could not avoid separate filings." So here we
14 are.

15 So then the question is is the PTO solely responsible
16 for the delay in causing the second-filed application to issue
17 prior to the first. And their arguments, as I understand it,
18 are basically, we sought extensions of time and we discontinued
19 an appeal -- this is on slide 72 now -- and that we failed to
04:54 20 accept an allowed claim in prosecuting the '471 patent. And
21 what Celltrion doesn't grapple with is why these events -- and
22 these are facts, they're facts we sought the extensions of
23 time, and we didn't accept this allowed claim, but why did they
24 cause the '471 patent to issue later? That's what the question
25 is. So let's take them one at a time. We sought four

1 extensions of time. That's true. They were permitted by
2 Congress. Extensions of time all by themselves don't excuse
3 the PTO from its delays.

4 THE COURT: But you said something a moment ago that I
5 don't think I've seen in the slides yet. And, you know,
6 defining the question with precision, the relevant question
7 with precision, is I think particularly important here. You
8 just said, I think, was the PTO solely responsible for the
9 delay?

04:55 10 MR. DISKANT: Sorry.

11 THE COURT: Is that the right test?

12 MR. DISKANT: I would say the right test is, is the
13 PTO solely responsible for the fact that the '471 patent issued
14 after the '195 and '272 patents. Because that's what we're
15 talking about. If it issued earlier, it would be a different
16 test.

17 THE COURT: Does any case use that formulation?

18 Fallaux I think says solely responsible for the delay.

19 MR. DISKANT: Usually they say solely responsible for
04:55 20 issuance of one patent rather than the other. The two-way --
21 this is Berg --

22 THE COURT: So I mean, is there a case that uses that
23 test?

24 MR. DISKANT: Berg says, "The PTO is solely
25 responsible for the delay in causing the second-filed

1 application to issue prior to the first." So to me, the right
2 question isn't whether --

3 THE COURT: Hold on just a second. What slide is
4 that?

5 MR. DISKANT: 71. To me, that's focusing on the right
6 question, because otherwise, you know, what's the question?
7 You have three months to file something, and you took three
8 months instead of two months and two weeks. I mean, if
9 anything you do other than instantaneous action is delay, then
04:57 10 there's no point to this test. To me the only point to the
11 test is comparative.

12 THE COURT: Hold on just one second. I want to find
13 that in *Berg*.

14 MR. DISKANT: That's on 1434.

15 THE COURT: I don't see it.

16 MR. DISKANT: Let me look. Well, I mean, is a similar
17 quote I can see right away, the court in *Braat*. That's in
18 heading A, the first full paragraph, "The Court in *Braat*
19 emphasized the more typical scenario in which despite common
04:58 20 inventive entities the two-way test applied when a later" --

21 THE COURT: I don't see that.

22 MR. DISKANT: You don't see that either?

23 THE COURT: I'm sorry. I'm looking at 1433. That's
24 the problem.

25 MR. DISKANT: Let me see if I can find the other

1 quote.

2 THE COURT: If I look on 1434, I probably will find
3 it.

4 MR. DISKANT: I unfortunately don't have it
5 highlighted here. I'm having trouble. Let me have somebody
6 look for it. Can somebody find that quote, the two-way test
7 may be appropriate. We'll get back to you, Judge.

8 THE COURT: All right.

9 MR. DISKANT: I've seen similar formulations. I was
04:59 10 about to read you one. I'll read you the one I did find. I'm
11 sorry. The one I did find was under section A, first
12 paragraph. That's not as clear. Anyway, to me this is the
13 only way this concept even makes sense. I mean, you shouldn't
14 be, you know, asking what people did every day. So, you know,
15 Ms. Elmore says she didn't delay. Here is the real nub of it.
16 The extensions of time didn't matter. Now I'm on slide 75.
17 What we've done is mark all the extensions of time in the
18 patents.

19 So let's assume there were no extensions of time.
05:00 20 Let's just take all the extensions of time out. Well, '471
21 still -- it doesn't make any difference. It's solely the PTO's
22 fault that the '471 issued later. The extension of time had
23 nothing to do with it. They have another argument that we took
24 an appeal, abandoned an appeal. Again, if we want to go into
25 the facts and bring in witnesses, these kinds of things

1 happened because strategies changed.

2 THE COURT: If the defendants say the extensions of
3 time did matter, would that be a genuinely disputed fact that
4 would have to be decided by the jury before this issue -- the
5 question of whether the two-way test applies could be decided
6 properly?

7 MR. DISKANT: I don't know what they would say. These
8 are just numbers. It seems to me if the question we're posing
9 is correct and we're correct on this -- although we haven't
05:01 10 moved for summary judgment on it, but it doesn't seem to me
11 it's possible to say the extensions of time are the reason the
12 '471 issued later. They just aren't. But, you know, we'll
13 hear what they have to say, and they'll say whatever they think
14 is appropriate.

15 But in any event, now the appeal is -- so we'll just
16 add the appeal. So now the period that's blanked in light blue
17 and green is the period during which prosecution was delayed by
18 taking and then discontinuing an appeal, which is a nine-month
19 period.

05:02 20 THE COURT: What slide that?

21 MR. DISKANT: Now we're at slide 78. And, you know,
22 once again, it just doesn't matter. I mean, the problem is
23 that the genus application for the '471 took too darn long
24 because of the PTO's fault, not because of the things they're
25 blaming us for.

1 And then their last point is, while the PTO said in
2 August 1997 that some claims were allowable and they seem to
3 think that we were obligated to grab those, and, you know, I
4 would say the right way to think about that is the PTO is
5 solely responsible for not realizing you're entitled to all
6 these claims. Why is it our fault that we want to keep going
7 to get claims we get that we're suing these guys for. So they
8 cited one case on this, this *Hubbell* case, which is so
9 different it's staggering. And in *Hubbell*, the examiner
05:03 10 actually allowed claims, the difference between allowable and
11 allowed.

12 THE COURT: What --

13 MR. DISKANT: I'm now at slide 82. You should know
14 that sometimes the PTO says a claim is allowable, which doesn't
15 allow you to get a patent but it allows you to come back and
16 re-write them. And so the difference between an allowable
17 claim and allowed claim is if they say it's allowed, you just
18 pay the fee and you get your patent.

19 In *Hubbell*, the examiner allowed claims, similar to
05:03 20 ones it wound up getting. He didn't pay his issue fee. He
21 abandoned the application. He later filed a new application.
22 The PTO is not responsible for that. In our case, the examiner
23 indicated some but not all claims would be allowable if
24 rewritten, and we continued to prosecute to get the claims we
25 were entitled to.

1 Again, Ms. Elmore testifies that the examiner never
2 suggested there was any impropriety in that. And again, just
3 look at the timeline. The PTO said some claims were allowable,
4 really as the other patents are about to issue. It didn't say
5 all the claims were allowable until a couple of years later.
6 That's PTO's problem, not ours. They're solely responsible for
7 taking all those years to say our claims were allowable.

8 And then just take a look at what I view is the real
9 problem, which is strangely inconsistent positions by the PTO
05:04 10 on these three patents. Now we're at slide 57.

11 THE COURT: 57?

12 MR. DISKANT: Excuse me. 87. I'm trying to get to
13 the end. Oh, we found the quote. Sorry. That's okay. It's
14 in *Hubbell*. But it's citing -- yes. Maybe it's the wrong page
15 on *Berg*. Try 1437.

16 Judge, we found the quote in *Hubbell*, most recent
17 case, and it cites *Berg*, and maybe we've got the wrong page
18 number. But this cites *Hubbell*, which is a 2013 case.

19 THE COURT: I have it.

05:05 20 MR. DISKANT: Okay. And what page is this? It's
21 right after heading C, "Two-Way Obviousness Analysis." And
22 there's a block quote.

23 THE COURT: Heading C.

24 MR. DISKANT: Heading C, then there's a block quote,
25 and right after the block quote, it says, "We have explained

1 that the two-way test is appropriate only in the unusual
2 circumstance where the PTO is solely responsible for the delay
3 in causing the second-filed application to issue before the
4 first." It cites *Berg* at 1437 for the same quote.

5 THE COURT: So that's a different page.

6 MR. DISKANT: I think we had the wrong page on our
7 slide. I apologize.

8 THE COURT: Hold on a second. Here it is. It's on
9 1437 at the end of the paragraph that starts at the top of the
05:06 10 page.

11 MR. DISKANT: Right. Sorry. Anyway, here is what's
12 happening in these three patents.

13 THE COURT: Okay.

14 MR. DISKANT: So as Your Honor has observed, we have
15 genus claims in the '471 and species claims in the two other
16 patents. For reasons that are inexplicable, the cA2 claims
17 slid through on the first two patents. Here is the '272. The
18 claims are submitted, they're rejected, and they're allowed in
19 the space of a year.

05:07 20 On the '195, again, they're submitted with the white
21 dot. They're rejected with the red dot. And then they're
22 allowed. And meanwhile, what happened on the '471, well, they
23 were submitted earlier, so we got an earlier application for a
24 cA2 claim, maybe a year or more earlier.

25 THE COURT: All right. I think I have this argument.

1 You didn't cause the -- I mean, your argument is that at least
2 looked at in the light most favorable to you the evidence
3 indicates that you, plaintiff, didn't cause any delay that
4 resulted in the '471 being issued after the other patents.

5 MR. DISKANT: Correct.

6 THE COURT: Okay. So let's assume -- although I
7 haven't found anything yet -- that you're entitled to the
8 two-way test. Then what?

9 MR. DISKANT: Well, then they lose, because their
05:09 10 obviousness argument under the two-way test is --

11 THE COURT: Well, okay. Go ahead.

12 MR. DISKANT: Their obviousness argument on the
13 two-way test fails. It quite readily fails. The relevant
14 question is -- I'll make it easier. Everyone agrees that in
15 the ordinary course --

16 THE COURT: What slide is that?

17 MR. DISKANT: This is 93. Double patenting is a
18 matter of what is claimed, and the specification cannot be used
19 as prior art in an obviousness-type double patenting analysis.
05:09 20 So that is the general or ordinary rule. And they don't
21 actually have an argument if that's correct in our case. In
22 fact, they don't even have an argument if it's not correct, as
23 I'll demonstrate. The asserted claims we looked at
24 previously -- now we're up to slide 94. "The '471 is an
25 antibody capable of binding TNF-a" --

1 THE COURT: Hold on a second. Let me ask Mr. Hurst,
2 remind me what the authority is for looking at the
3 specification.

4 MR. HURST: *Sun, Gemzar and Pfizer.*

5 THE COURT: So how do you respond to that?

6 MR. DISKANT: That's what I'm going to do.

7 THE COURT: What's that?

8 MR. DISKANT: Yes. How I respond to that -- let me
9 just do that quickly. Again, we have all the science. We have
05:10 10 evidence. So we have two non-obviousness arguments.

11 THE COURT: No. What I'm talking about now is you
12 cite AbbVie here. "Specification cannot be used as prior art
13 in an obviousness-type double patenting analysis." Is this on
14 the two-way test?

15 MR. DISKANT: Yes. It's on any test. They agree with
16 that. That's not their argument. They agree that ordinary
17 double patenting you don't look at patent spec. You only look
18 at the claims. Here is their argument. Let me go back.

19 Okay. It's based on a case called *Sun*, which
05:11 20 Mr. Hurst argued. What you see here is a compound standing
21 alone. And this is a claim to a nuclear side of the formula,
22 whatever. And if you look at a compound standing alone, you
23 have no idea what it is useful for. It could be car polish, it
24 could be laundry detergent, it could be a pharmaceutical, it
25 could be anything. Because giving the chemical formula for

1 something doesn't tell you what it's useful for. And so the
2 Sun case says, "We acknowledge the general rule that an earlier
3 patent specification is not available for obviousness-type
4 double patenting. However, a court considering a claim to a
5 compound must examine the patent specification to ascertain the
6 coverage of a claim because a claim to a compound standing
7 alone does not adequately disclose the patentable bounds of the
8 invention."

9 THE COURT: What slide is that?

05:12 10 MR. DISKANT: This is slide 103. It doesn't have a
11 cite. I'm so sorry. It's 1389.

12 THE COURT: Just one second.

13 MR. DISKANT: Sure.

14 THE COURT: I don't see it on 1389.

15 MR. DISKANT: It's not. It's on 1387. I apologize.
16 It's at the end of paragraph --

17 THE COURT: Okay. So I think Mr. Hurst emphasized
18 this.

19 MR. DISKANT: Yes, he did, but he didn't emphasize the
05:13 20 words "standing alone."

21 THE COURT: Let me find that.

22 MR. DISKANT: Sure. It's at the end of the paragraph.
23 "Furthermore, we reject."

24 THE COURT: Okay. It says, "As we recognize in
25 Geneva, a court considering a claim to a compound must examine

1 the patent specification to ascertain the coverage of the claim
2 because a claim to a compound standing alone does not
3 adequately disclose the patentable bounds of the invention."

4 Is the '471 a patent for a compound?

5 MR. DISKANT: Not a compound standing alone, no.

6 THE COURT: I'm going to get to that. Is it a patent
7 for a compound?

8 MR. DISKANT: Sure, yes.

9 THE COURT: Then here it says -- okay. "Compound
05:15 10 standing alone," but it says "the court," me, "has to examine
11 the patent specification."

12 MR. DISKANT: If it is a claim to a compound standing
13 alone. This body of cases, Judge, is all about claims like
14 that.

15 THE COURT: Is that graphic in *Sun*?

16 MR. DISKANT: The graphic isn't in *Sun*, but that's
17 what they were discussing.

18 THE COURT: Well, how do I know that?

19 MR. DISKANT: You can read, "The compound standing
05:15 20 alone."

21 THE COURT: So the belief --

22 MR. DISKANT: With all respect, Judge --

23 THE COURT: This may be very obvious to you. It says
24 I "must consider the specification to ascertain the coverage of
25 a claim because a claim to a compound," then it quotes *Geneva*,

1 "standing alone." It seems to be saying -- what number is that
2 slide?

3 MR. DISKANT: The slide is 101.

4 THE COURT: 101, which you say depicts a compound all
5 by itself. It seems to me that what it's telling me in that
6 sentence is I have to look at the specification. Otherwise,
7 the compound stands alone.

8 MR. DISKANT: Respectfully, Judge, there are three
9 cases in this line of cases. They're all claims to compounds
05:16 10 standing alone, namely, bare formulas, in which a reader would
11 have no idea what they were to be used for, what their utility
12 was.

13 THE COURT: So in the claim term here --

14 MR. DISKANT: In the claim term here, we have "a
15 chimeric antibody capable of binding the TNF-a." That is a
16 very important utility. TNF-a is known to cause inflammation.
17 TNF-a is related to a whole variety of diseases, and an
18 antibody that's capable of binding to TNF-a is useful.

19 Mr. Hurst said this related to the patent law that a
05:17 20 patent must have some use. The compound we just saw in *Sun* has
21 no use. I mean, it's just a collection of molecules. This is
22 a compound with a use of great interest to the scientific
23 community. So it just isn't what those cases are about.

24 THE COURT: Okay.

25 MR. DISKANT: There's a second reason, though. I'm

1 sorry. Did I interrupt you?

2 THE COURT: Go ahead.

3 MR. DISKANT: There's a second reason. Sorry.

4 THE COURT: No. Go ahead.

5 MR. DISKANT: Which is, even if Mr. Hurst was right,
6 and respectfully he's not, this has a utility. But even if he
7 were right, the *Sun* exception doesn't apply to the other
8 non-obviousness issue here. There are two issues on
9 obviousness, at least for purposes of this discussion.

05:18 10 One is, are the methods of use obvious. That is, the
11 methods of using it to treat Crohn's and rheumatoid arthritis.
12 They're not obvious from the claim. Counsel argues that they
13 are disclosed in the specification. And we say you don't look
14 at them because *Sun* doesn't allow you to.

15 Okay. Let's say we're wrong. Separate and apart from
16 that, there are claims to a genus in the '471 and species in
17 the two other patents. So the broad claims and the narrow
18 claims. *Sun*'s got nothing to do with that. That's not a
19 utility question anymore. That's a specific claiming issue.
05:18 20 We claimed in the '471 -- in the '471 we claim a group of
21 antibodies, and in the other claims we have a cA2 antibody. So
22 they have --

23 THE COURT: What number is that one?

24 MR. DISKANT: This is 107 and 108 and 109.

25 THE COURT: When you do your slides in the future, if

1 you do them again, you'll try to get the numbers on them. I
2 can't see the numbers.

3 MR. DISKANT: I can't see them either, but they're
4 there.

5 THE COURT: It just helps, because this is all so
6 good.

7 MR. DISKANT: I apologize, Judge. I'm squinting each
8 time. That's 107, 108 and 109.

9 THE COURT: I can't see them.

05:19 10 MR. DISKANT: Sadly, they're faded. But in any event,
11 this is completely unrelated to, you know, looking at the spec
12 to see utility. This is, "I have a patent on a group of
13 antibodies, and there are other patents on specific antibodies.
14 Why are the specific antibodies obvious in light of the genus
15 claim?" There's a whole body of law on this subject.

16 The fact that a claim species is encompassed by a
17 prior art genus is not sufficient to establish a case of
18 obviousness. They've got no evidence on this. They didn't put
19 in an expert. They have nothing. So I frankly think their *Sun*
05:20 20 argument is wrong on the facts, and even if it were right, it
21 doesn't get to a declaration as a matter of that these two
22 patents are obvious in light of the '471. You just can't get
23 there from here. That's my argument.

24 THE COURT: It's 5:20. We've been at this for a long
25 time. But if there's a general genus patent that includes the

1 particular -- for a group of antibodies to treat rheumatoid
2 arthritis and then there's another patent for a specific
3 antibody that treats rheumatoid arthritis, why isn't the second
4 more specific one obvious in light of the first more general
5 one that references the same use?

6 MR. DISKANT: Well, the more general one, as I just
7 said, references binding TNF-a. It doesn't reference the
8 method of treatment. But separate and apart from that, there
9 is just a wide body of developed law that you need to have a
05:21 10 scientific inquiry into whether a particular embodiment of a
11 genus is obvious in light of the genus.

12 It may be, you know, human beings are good runners.
13 Does that mean, you know, some Olympic champion -- that I can't
14 name because I've been doing this -- is a good runner? The
15 species claims are just different in kind, and you certainly
16 can't just invalidate them on no evidence whatsoever.

17 THE COURT: So you're saying there needs to be a trial
18 on this motion for summary judgment with regard to
19 reexamination?

05:22 20 MR. DISKANT: With regard to the obviousness issues.
21 So to just sort through what I just said. There is the safe
22 harbor argument. If you reject it, then you have to address
23 the two-way test issue. And I say that the two-way test raises
24 fact issues both about whether it applies, and if it applies,
25 whether the patents are obvious.

1 THE COURT: Is *Braat* the only case that's ever applied
2 the two-way test?

3 MR. DISKANT: I can't answer that question. It may
4 be. I'm not quarreling with the observation that it's
5 infrequent. It's more frequently applied by the PTAB, and we
6 cited it in the Patent Office, and we cited a bunch of cases to
7 that effect. But yes, it's unusual. But I can't imagine why
8 it took so long for the PTO to issue our '471 patent when they
9 did the other ones quickly, and it wasn't because of anything
05:23 10 we did.

11 THE COURT: Okay. All right. Mr. Hurst, is there
12 anything you'd like to say of a relatively piffy nature in
13 response to this?

14 MR. HURST: I think I have five minutes. Would you
15 prefer to do it in the morning?

16 THE COURT: No. I'm going to decide these matters
17 tomorrow.

18 MR. HURST: Let me take them one at a time. I'm going
19 to be really brief on the safe harbor, Your Honor. You asked
05:23 20 do I have the discretion to depart from the statutory language,
21 which requires the filing of a divisional. And I would
22 suggest, respectfully, Your Honor, you don't, because Congress
23 took that discretion away from you.

24 *Pfizer, Amgen, Searle*, they all treat it as a matter
25 of statutory construction. They said ultimately, essentially,

1 divisional means divisional. The '471 was a CIP.

2 In terms of just the equities -- and you don't need to
3 get there. But that statute has said divisional since 1952.

4 THE COURT: I think I got this.

5 MR. HURST: I understand. Just a really quick point
6 is, it wasn't like Janssen didn't have options. They said,
7 Well, we wanted to add matter to this, new matter to this.
8 Therefore we had to call it a CIP. All they had to do was file
9 the divisional because that's what the statute says, and then
05:24 10 they could file a new application off the divisional to add the
11 new matter. There were options for them to avoid not complying
12 with Section 121.

13 Next, if you have no questions on the safe harbor -- I
14 didn't hear very much at all on the '272 patent, which was
15 filed on the same day as the '471 patent. Your Honor, that is
16 an independent basis to reject the two-way test in favor of the
17 one-way test. And I just wanted to point out that the --

18 THE COURT: They say -- plaintiff says that the Patent
19 Office instructed them to break up the -- you know, to file
05:25 20 multiple applications. So it was natural to file them on the
21 same day.

22 MR. HURST: And when you do file them on the same day,
23 the very fundamental reason to even consider the two-way test
24 is gone. They directed you -- the quote that everybody was
25 having trouble finding in *Berg*, this is the test, the one that

1 they cited to Your Honor. The two-way test may be appropriate.
2 However, in the unusual circumstance that the PTO is solely
3 responsible for the delay in causing the second-filed
4 application to issue prior to the first application, every
5 single formulation that I'm aware of the two-way test has that
6 formulation where they're comparing temporally the first-filed
7 versus the second-filed. And when you file on the same day --
8 and *Berg* I think does make this clear. I know it focuses on a
9 different issue. But it makes it clear that's also one of the
05:26 10 requirements and that when you simultaneously file, they said,
11 you're taking a risk. The MPEP says the same thing. If you
12 file on the same day, you don't even get out of the starting
13 blocks on a two-way test and you just stick to the one-way
14 test.

15 Now, on the two-way test itself, the way -- and I
16 understand the argument, and I understand the logic of the
17 argument, too. What they're saying is if you subtract all of
18 the things we're responsible for, not taking an appeal, taking
19 all the extensions of time, the '471 patent still would have
05:27 20 issued later in time as compared to the earlier patents.
21 That's the argument, right? The problem with the argument is
22 it ignores that no case has ever done the math like that. All
23 they ask is, Were you responsible in part for the delay in the
24 ultimate issuance of the patent.

25 THE COURT: That doesn't seem to be the language that

1 Mr. Diskant was pointing me to in *Berg* and the other cases.
2 It's in the delay that caused the first-filed to be issued
3 second.

4 MR. HURST: Right. And I agree with that. When
5 you're calculating that delay, up until the time it gets issued
6 later in time, if both parties contributed something to that
7 process, the two-way test doesn't apply. That's why, Your
8 Honor, it's so rarely applied.

9 Imagine if Janssen was right that you did the math
05:27 10 they did, it wouldn't be really applied because there's always
11 going to be competing contributions. Here is why it's so
12 critically important. When they did -- slide 76. You don't
13 have to look at it because it's quick. They did a hypothetical
14 where they removed all of their extensions of time, and they
15 said the '471 patent still would have issued later in time, but
16 it would have issued two years earlier. And therefore, the
17 extension of time that's created by the later-expiring patent
18 would have been shorter, and that's why any delay that the
19 patentee --

05:28 20 THE COURT: Let me see if I understand this because it
21 is important that this doesn't get lost in technicality. So
22 the argument you're making now is, if I look at slide 76, which
23 I'm not going to do, and accept the assumptions, assertions,
24 the '471 still would have issued after the other two patents
25 but two years earlier than it did, and because it actually

1 issued two years later, Janssen gets two more years of patent
2 protection at \$4 billion a year.

3 MR. HURST: That's right.

4 THE COURT: So it's an \$8 billion issue.

5 MR. HURST: It's an \$8 billion issue. The current
6 expiration date, absent invalidation, is September of '18. If
7 you just subtract the extensions of time, it would have been
8 October of 2016.

9 THE COURT: Just when you want to sell.

05:29 10 MR. HURST: Exactly, it would be perfect. But I guess
11 the point is this. You don't segregate it that way. You look
12 at, was it delayed and was there a contribution in the delay
13 from both parties? If the answer to that is yes, the two-way
14 test, which is so rarely applied, should not apply.

15 Finally, on Sun -- I guess just to frame the issue,
16 the compound -- it's a compound claim. It says, We claim an
17 antibody, and it describes that antibody as an antibody capable
18 of binding to TNF. That, Your Honor, is not a utility under
19 the law. It's a property of the compound. It's something
05:30 20 that's capable of binding to TNF.

21 To actually make it useful, you actually have to give
22 the drug to somebody who actually needs TNF binding. Giving it
23 to me would do nothing. So it is a compound patent, and it
24 does not disclose a use for that compound. And what Sun tells
25 you to do, what Pfizer tells you to do is read the

1 specification. What does the specification say? You use that
2 compound to treat RA and to treat Crohn's.

3 He had a separate argument. Just really brief. He
4 had a separate argument, species, genus. Your Honor, I don't
5 think that's a serious argument. The '471 patent claims a
6 group of antibodies. Under *Sun* and *Pfizer* you read the
7 specification. The specification says, Use these antibodies
8 that I'm claiming to treat Crohn's and also to treat RA. One
9 of those antibodies in that group is infliximab, which is the
05:31 10 very antibody in the '192 patent and the '272 patent that is
11 claimed for use to treat Crohn's and RA.

12 Thank you, Your Honor.

13 THE COURT: All right. It's 5:30. Here is how I
14 intend to proceed. I had ordered you to be available today,
15 tomorrow and Thursday for these hearings, since my goal is to
16 decide all the pending matters orally.

17 Today has been very helpful, but it's taken longer
18 than I thought and you thought. But it's okay. I don't think
19 the Federal Circuit will give you this much time. No, but this
05:31 20 is good.

21 I want you to come back tomorrow at 1:00. I will use
22 tomorrow morning to, at a minimum, further develop my thoughts
23 with regard to the *Gilead* motion, and hopefully I'll have a
24 ruling at 1:00 on the reexamination motion as well. That has
25 more parts. Then I want to hear your argument on the '083.

1 And just so the defendants don't get too excited and
2 the plaintiffs too depressed, I ordinarily wouldn't do this,
3 but I think there's a good reason to do it here. My tentative
4 view is that the plaintiffs are right. "Cell culture media"
5 just means cell culture media. It's defined in the technical
6 dictionaries. It's unmodified. It means what it says.

7 So if that's my ruling tomorrow or Thursday morning,
8 the '083 will survive even if the '471 doesn't. And I tell you
9 that -- I've suggested this when we were in the lobby last time
05:33 10 I saw you. But as I recall, I didn't order it. But you
11 brought your business people here. And now you have tomorrow
12 morning. And, you know, this is business. And I do feel both
13 because of the statute that contemplates that these issues will
14 be decided and that six months after approval, you know, to try
15 to do what my friend Lamar Smith thought we were going to do if
16 he had a role in this, to try to make this work.

17 I know it's very consequential. And you know, I'd
18 like to take time and write a long and elegant decision, but
19 I'm immersed in this. I think the most appropriate thing for
05:34 20 me to do is to decide orally anything I can decide orally.
21 But, you know, I could order it, but I hope you use tomorrow
22 morning to continue your discussions. And that's why I tell
23 you what my tentative view on the '083 is.

24 My tentative view to expedite the trial, I'm inclined
25 to deny that. We set a schedule that the defendants would have

1 reasonably relied on and the plaintiff decided not to move for
2 a preliminary injunction -- you can change your mind -- but
3 that's in effect what an expedited trial appears to me to be at
4 the moment. So that if the '083 survives, I would consolidate
5 the second case with the first one. Does that have '083 claims
6 in it, too?

7 MS. ROYZMAN: Yeah.

8 THE COURT: It does. And you seem to think both can
9 be prepared for trial in February?

05:35 10 MR. DISKANT: Right.

11 THE COURT: I wrote about this when I denied the stay
12 in the *Columbia* multidistrict litigation in 2004. I probably
13 said it when I denied the stay of this case. You know, my
14 sense in these patent cases is that each of your first choices
15 is to win. But, you know, if you can't get a decisive,
16 definitive final answer, then certainty is very important.

17 So you're getting more information, and you'll have
18 more before you go home on Thursday, but at some point the
19 defendant is going to be able to sell its product. Whether
05:36 20 it's in 2016 or 2018 is the issue. It's a matter of money,
21 it's business. You told me you've been talking, and if you
22 want, I'll seal this portion of the discussion. Perhaps I'll
23 refer you to settlement discussions we had in the lobby, or at
24 least about the process.

25 Are you willing to talk to each other tomorrow

1 morning?

2 MR. HURST: I think the answer is absolutely yes.

3 MR. DISKANT: Yes, Your Honor.

4 THE COURT: All right. And if somehow you settle the
5 case before 1:00, let me know.

6 (Laughter)

7 But I'll see you at 1:00. We'll keep going. You'll
8 have my best answer on I think all three of the motions before
9 you go home on Thursday. If for some reason I can't decide the
05:37 10 reexamination motion tomorrow, if I haven't worked through it
11 sufficiently, we'll do the '083 because the reexamination
12 motion is an alternative basis. If I decide the *Gilead* motion
13 in favor of the defendants, in another case I might just say
14 the reexamination motion is moot. I'm not inclined to do that
15 in this case because this is just all so consequential to you
16 and ultimately to the public.

17 All right. I'm ordering you to do what you would do
18 anyway, which is order the transcript, although the court
19 reporter doesn't need to prepare it by tomorrow. And I'll
05:38 20 thank my staff for their dedication in staying here almost
21 until 6:00, and I'll see you at 1:00 tomorrow.

22 Court is in recess.

23 (Adjourned, 5:38 p.m.)

24

25

1
2 CERTIFICATE OF OFFICIAL REPORTER
3
4

I, Kelly Mortellite, Registered Merit Reporter
and Certified Realtime Reporter, in and for the United States
District Court for the District of Massachusetts, do hereby
certify that pursuant to Section 753, Title 28, United States
Code that the foregoing is a true and correct transcript of the
stenographically reported proceedings held in the
above-entitled matter and that the transcript page format is in
conformance with the regulations of the Judicial Conference of
the United States.

13 Dated this 23rd day of August, 2016.
14

15 /s/ Kelly Mortellite
16 _____
17 Kelly Mortellite, RMR, CRR
18 Official Court Reporter
19
20 10:33
21
22
23
24
25

EXHIBIT 9

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY**

Plaintiffs,

v.

**CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.**

Defendants.

Civil Action No. 1:15-cv-10698

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY
JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 6,284,471
FOR OBVIOUSNESS-TYPE DOUBLE-PATENTING**

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Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. (together, “Celltrion”) and Hospira, Inc., respectfully submit this memorandum in support of their Motion for Summary Judgment of Invalidity of asserted claims 1, 3 and 5–7 of U.S. Patent No. 6,284,471 (“the ’471 patent”) for obviousness-type double-patenting over any one of U.S. Patent Nos. 6,790,444 (“the ’444 patent”), 5,656,272 (“the ’272 patent”), or 5,698,195 (“the ’195 patent”).

INTRODUCTION

Straightforward application of a “bedrock principle of our patent system” compels this Court to find the asserted claims of the ’471 patent invalid as a matter of law. This “bedrock principle” holds that “when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention.” *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014). That “principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention . . . because the inventor holds another later-expiring patent” on those “obvious modifications.” *Id.* The doctrine of double patenting thus forbids a patent owner from obtaining more than one patent on the same or obvious variants of the same invention if those patents have different expiration dates. But Janssen has done just that—asserting a later-expiring patent that claims the same invention as its already-expired patents—which mandates a finding of invalidity of the later-expiring patent for double patenting.

Janssen’s expired ’444 patent claims the same antibodies covered by the claims of Janssen’s presently-asserted ’471 patent. The pertinent claims in those two patents are nearly word-for-word identical. And whatever trivial textual differences exist, there is no possible dispute that the later-expiring ’471 patent claims either the same or an obvious variant of the inventions claimed in the ’444 patent. Indeed, when faced with Celltrion’s obviousness-type

double patenting defense as part of the pre-litigation exchange of positions under the Biologics Price Competition and Innovation Act (BPCIA) statute, Janssen did not argue otherwise.

Instead, Janssen argued that the '444 patent could not qualify as an invalidating "reference patent" because it happened to *issue* after—even though it *expired* before—the '471 patent. But the Federal Circuit already rejected that very argument in its 2014 *Gilead* decision, holding that courts should "look[] to the expiration date instead of issuance date" to assess double patenting. *Id.* at 1216. Under *Gilead*, Janssen's patent monopoly on this invention should have ended with the expiration of the '444 patent in 2011. The Court should thus find the '471 patent invalid for double patenting.

In fact, the Patent Office has *already* held the '471 patent invalid during reexamination for double patenting over *other* expired patents that Janssen owns: the '195 and '272 patents. In a pending Patent Office proceeding—which could take years to resolve—Janssen is relying on various inapplicable technicalities to attempt to overturn the Patent Office's decision. But none of those arguments have any merit, and the same grounds on which the Patent Office has rightfully relied provide further independent bases for finding that the '471 patent is invalid for double patenting. The asserted claims of the '471 patent should be declared invalid.

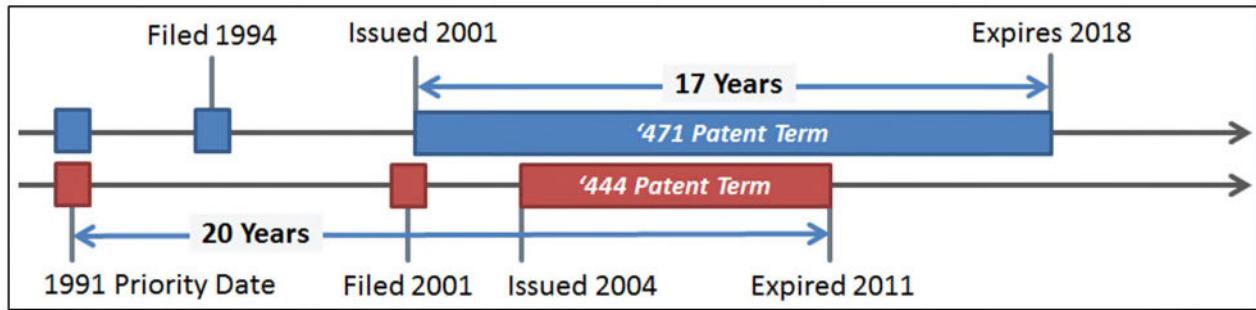
I. The Court Should Grant Summary Judgment Of Invalidity Of The '471 Patent For Double Patenting Using Either The '444, '195 Or '272 Reference Patents

Janssen is asserting its '471 patent against Defendants in this litigation. Facts 1, 2. Janssen is also the owner of the expired '444 patent. Fact 3. Both patents list the same set of inventors, relate back to several of the same priority patent applications, and share the same earliest effective filing date of March 18, 1991. Fact 4. The '471 patent resulted from U.S. Patent Application No. 08/192,093, filed on February 4, 1994, whereas the '444 patent resulted from U.S. Patent Application No. 09/756,301, filed on January 8, 2001. Facts 5, 6.

The two patents' different filing dates result in different expiration dates. Facts 5, 6. Patents resulting from applications filed before 1995, such as the '471 patent, have a term of seventeen years from the patent issue date or twenty years from the earliest effective filing date, whichever is longer. *See* 35 U.S.C. § 154(a)(2), (c)(1); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547–1548 (Fed. Cir. 1996). In 1995 the law changed, such that patents resulting from applications filed after 1995, such as the '444 patent, have a term of twenty years from the patent's earliest effective filing date regardless of issue date. *Id.*

The Patent Office issued the '471 patent on September 4, 2001. Fact 5. It issued the '444 patent on September 14, 2004. Fact 6. Because of their filing dates, the '444 and '471 patents are governed by different means for calculating patent terms, resulting in the later-issued '444 patent having expired twenty years after its 1991 effective filing date in 2011, while the earlier-issued '471 patent does not expire until seventeen years after its 2001 issue date in 2018.

Facts 5, 6. The timeline below shows the different patent terms:



Both the '444 reference patent and the '471 patent-in-suit claim the same “chimeric antibody,” i.e., infliximab. Facts 18–20. An antibody is a large, Y-shaped protein (i.e., a polypeptide) used by the immune system that recognizes unique molecules; a chimeric antibody is an antibody designed by man to contain non-naturally occurring protein sequences. Facts 21, 22. The chimeric antibody of the '471 and '444 patents is known as infliximab or “cA2,” and it

recognizes a protein involved in inflammation known as tumor necrosis factor alpha (TNF- α).

Fact 23. By binding to this protein, infliximab is used to treat autoimmune disorders. Fact 24.

Both the '471 and the '444 patents claim infliximab—in some claims by reciting the corresponding nucleic acid sequences, and in other claims, by reciting the corresponding amino acid sequences (i.e., the chains of amino acids forming the polypeptide), but they are two ways of saying the same thing. Fact 25. The '444 patent includes claims that are nearly verbatim to those of the '471 patent. *See Appendix 1 (claim chart); Facts 13, 14.* The only difference is that the '444 patent claims recite a single antibody, infliximab, rather than the group of antibodies claimed by the '471 patent. The group of antibodies claimed by the '471 patent includes infliximab. Fact 20. In other words, the '471 patent recites a genus of antibodies, and the '444 patent recites a single species (infliximab) contained within that genus.

The '195 and '272 patents, which share the same effective filing date of March 18, 1991 as the '471 patent, claim methods of treatment using infliximab. Facts 4, 16, 17. Both the '195 and '272 patents expired in 2014. Facts 7, 8. During reexamination of the '471 patent, the examiner at the Patent Office rejected the claims of the '471 patent under the doctrine of obviousness-type double patenting in view of both the '195 and '272 patents. Fact 27. Janssen has appealed that determination. Fact 27.

II. Legal Standards

A. Summary Judgment

Summary judgment should be granted when “there is no genuine dispute as to any material fact” and “the movant party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue is “genuine” when a reasonable fact-finder could find for the non-moving party; a fact is “material” when it might affect the outcome of the suit under the applicable law. *Morris v. Gov’t Dev. Bank*, 27 F.3d 746, 748 (1st Cir. 1994). The non-moving party bears the burden of

placing at least one material fact into dispute after the moving party shows the absence of any disputed material fact. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 15 (1st Cir. 1994) (discussing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

B. Obviousness-Type Double Patenting

Double patenting is a question of law. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352 (Fed. Cir. 2009). It is “intended to prevent a patentee from obtaining a timewise extension of [a] patent for the same invention or an obvious modification thereof.” *Sun Pharma. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010) (quoting *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008)). “It is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it [to the public] at the end of his patent term.” *Gilead Sci.*, 753 F.3d at 1212. By “limiting a patentee to one patent term per invention or improvement,” the doctrine of double patenting “preserve[s] the public’s right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements.” *Id.* The doctrine applies so long as the earlier and later expiring patents have at least one common inventor, subject to a narrowly-construed safe harbor in 35 U.S.C. § 121 (discussed below). *In re Hubbell*, 709 F.3d 1140, 1145–46 (Fed. Cir. 2013).

III. The ’471 Patent Is Invalid In View Of The ’444 Patent Under The Doctrine Of Obviousness-Type Double-Patenting

In response to Defendants’ pre-suit explanation that the ’471 patent is invalid for double patenting over the ’444 patent, Janssen failed to assert that the ’471 patent was patentably distinct from the ’444 patent. Fact 40. That leaves the only issue that Janssen has ever raised—whether the later-issuing, earlier-expiring ’444 patent can serve as an invalidating double-

patenting reference against the earlier-issuing, later-expiring '471 patent. Because as a legal matter the answer to that question is clearly yes under the Federal Circuit's decision in *Gilead*, this Court should enter summary judgment of invalidity.

A. The Claims Of The '471 Patent Are Not Patentably Distinct From The Claims Of The '444 Patent

Under the doctrine of obviousness-type double patenting, a claim in a second patent is invalid if it is "not patentably distinct from the claims of [a] first patent," *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985), such that "the later patent claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (citations omitted). The analysis may "tak[e] into account the skill of the art and prior art other than the invention claimed in the [earlier] patent." *Longi*, 759 F.2d at 892.

Here, it is beyond dispute that at least claims 1 and 2 of the '444 patent anticipate all of the asserted claims of the '471 patent. It is black letter law that "a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960); *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989). That is precisely the case here. Claim 1 of the '444 patent claims infliximab, also known as cA2: "The chimeric antibody cA2." Fact 19. Each of the asserted claims of the '471 patent-in-suit (claims 1, 3 and 5–7) covers a genus that includes cA2—otherwise, there could be no allegation of infringement. Fact 20. Because the species of '444 patent claim 1 anticipates the asserted claims of the '471 patent, those genus claims are not patentably distinct.

Claim 2 of the '444 patent provides an independent basis for finding no patentable distinction, because it likewise anticipates the asserted claims of the '471 patent. Indeed, the asserted claims of the '471 patent are recited nearly *verbatim* in claim 2 of the '444 patent. *See*

Appendix 1 (claim chart); Facts 13, 14. There are only three textual differences, none of which makes any possible *patentable* difference. The first is highlighted below:

'444 Patent (Expired 2011)	'471 Patent (Expires 2018)
Claim 2	Claim 1
A chimeric antibody comprising at least part of a human IgG1 constant region and	A chimeric antibody comprising at least part of a human immunoglobulin constant region and
at least part of a non-human immunoglobulin variable region,	at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human [tumor necrosis factor] TNF α ,	said antibody capable of binding an epitope specific for human tumor necrosis factor TNF α ,
wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.	wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

The “human immunoglobulin constant region” is a genus as shown by dependent claim 6 of the ’471 patent, which further recites that the “IgG1” is one of the species within the “the human immunoglobulin constant region.” Fact 13. Thus, the ’444 patent recites a species of the genus recited by the ’471 patent, which is not a patentable distinction as a matter of law. *Slayter*, 276 F.2d at 411; *Gosteli*, 872 F.2d at 1010.

The second textual difference is found in claims 5 and 6 of the ’471 patent:

'444 Patent (Expired 2011)	'471 Patent (Expires 2018)
Claim 2	Claim 5
A chimeric antibody	A chimeric antibody
comprising at least part of a human IgG1 constant region and	comprising two light chains and two heavy chains, each of said chains comprising at least part of a human immunoglobulin constant region
at least part of a non-human immunoglobulin variable region,	and at least part of a non-human immunoglobulin variable region,
said antibody capable of binding an epitope specific for human [tumor necrosis factor] TNF α ,	said variable region capable of binding an epitope of human tumor necrosis factor hTNF α ,

'444 Patent (Expired 2011)	'471 Patent (Expires 2018)
wherein the non-human immunoglobulin variable region comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.	wherein said light chains comprise variable regions comprising SEQ ID NO: 3 and said heavy chains comprise variable regions comprising SEQ ID NO: 5.
	Claim 6 A chimeric antibody according to claim 5, wherein the human immunoglobulin constant region is an IgG1.

Claim 2 of the '444 patent states that the chimeric antibody comprises “at least part of a human IgG1 constant region,” particularly identifying the immunoglobulin as an IgG1. Fact 14. Claim 5 of the '471 patent more broadly recites that the chimeric antibody contains a human immunoglobulin constant region. Fact 13. Thus, the subject matter of claim 5 of the '471 patent is broader than claim 2 of the '444 patent, but the subject matter of claim 2 falls squarely within the scope of claim 5.¹ Claim 2 of the '444 patent thus anticipates claim 5 of the '471 patent (and by extension claim 6). Indeed, claim 6 of the '471 patent more particularly specifies that the “human immunoglobulin constant region” of claim 5 “is an IgG1,” and claim 2 of the '444 patent specifically recites “a human IgG1 constant region.” Facts 13, 14. There is thus no patentable distinction here either.

The third and final insignificant textual difference is found in claims 3 and 7 of the '471 patent. *See Appendix 1*; Fact 13. Both claims 3 and 7 refer to a “polypeptide *encoded* by a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 4,” while claim 1 of the '471 patent refers to “an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.” Fact 13. Those are just different ways of saying the same thing. Fact 25. SEQ ID NOS: 2 and 4 are nucleic acids (DNA) that serve as a

¹ Moreover, the “non-human immunoglobulin variable region” is defined as comprising the same amino acid sequences (SEQ ID NOS: 3 and 5) as the “light” and “heavy chains” of the '471 patent. Fact 15.

template for a corresponding polypeptide (amino acid sequence).² And the polypeptide encoded by SEQ ID NO: 2 is the same as the polypeptide of SEQ ID NO: 3; the polypeptide encoded by SEQ ID NO: 4 is the same as the polypeptide of SEQ ID NO: 5. Fact 26. Claims 3 and 7 of the '471 patent thus recite *exactly* the same chimeric antibody as claims 1 and 2 of the '444 patent, just using different words. Fact 25.

Accordingly, at least claims 1 and 2 of the '444 patent anticipate each of the asserted claims of the '471 patent, which is presumably why Janssen has never before made any attempt to argue any patentable distinctions between the '444 and '471 patent claims. *See* Fact 40.

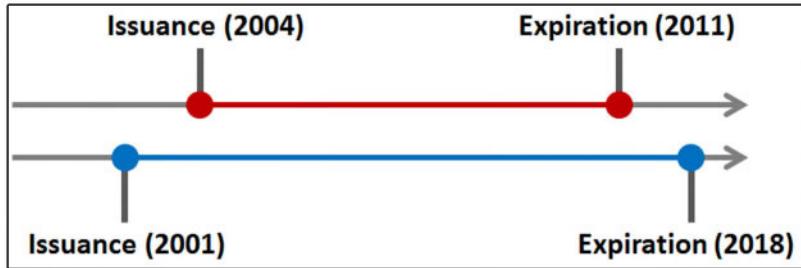
B. Under Gilead, The Earlier-Expiring '444 Patent Can Be Used As A Double-Patenting Reference To Invalidate The Later-Expiring '471 Patent

Janssen cannot escape double patenting based on the relative *issue* dates of the '444 and '471 patents, because only *expiration* dates matter. In a typical double-patenting scenario, an earlier-issuing and earlier-expiring patent (the red line below) invalidates a later-issuing and later-expiring patent (blue line):



Here, however, an intervening change in the law governing patent terms resulted in the earlier-expiring '444 patent (the red line below) issuing *after* the later-expiring '471 patent (blue line):

² A polypeptide can be specified either by its amino acid sequence or by the nucleic acid sequence that results in the same polypeptide. *See In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (stating it is “a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.”).



After the change in the law governing patent term, there was some uncertainty whether an earlier expiring patent could serve as a reference patent for double patenting if it was later-issuing. The Federal Circuit's 2014 *Gilead* decision put any uncertainty to rest. 753 F.3d at 1217.

Under *Gilead*, what matters for a double-patenting reference is whether it *expires* before the second patent, not whether it *issued* before the second patent. The Federal Circuit addressed the precise issue before this Court—that is, “whether a later-issued patent can serve as a double patenting reference for an earlier-issued patent if the later [issued] one expires first.” *Id.* at 1214. To answer that question, the court relied heavily on the “bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention.” *Id.* It observed: “that principle is violated when a patent *expires* and the public is nevertheless barred from practicing obvious modifications of the invention.” *Id.* (emphasis added). From there, the Court looked solely to the relative *expiration* dates of the two patents to conclude that the “bedrock” principle was being violated:

The '375 patent expires on February 27, 2015. Thus, come February 28, 2015, the public should have the right to use the invention claimed in the patent and all obvious variants of that invention. That was the condition upon which the '375 patent was issued to the inventors. But the public will not be free to do so. The '483 patent does not expire until December 27, 2016, and it ... covers obvious modifications of the invention claimed in the '375 patent. The '483 patent, therefore, extends the inventors' term of exclusivity on obvious variants of the invention claimed in the '375 patent for an additional twenty-two months past the expiration of the '375 patent. That plainly violates the public's right to use the

invention claimed in the '375 patent and all obvious variants of it after the '375 patent expires.

Id. (internal citations omitted). That is enough to resolve the key issue before the Court here.

Gilead went further, however, specifically refusing the argument that the *issue* date has any bearing on the analysis. The Court saw “little import . . . in the fact that the '483 patent issued first.” *Id.* It reviewed earlier case law referring to the *issue* date, and noted that in those cases the issue date merely served “as a reliable stand-in for the date *that really mattered*—patent expiration.” *Id.* at 1215 (emphasis added). In cases, such as this one, “in which a patent that issues first does not expire first,” the *Gilead* Court made clear “it is the comparison of [the] patent expiration dates that should control.”³ *Id.* The Court also discussed why reliance “on issuance date” would “have several shortcomings,” including that patent terms could be subject to gamesmanship, and that patents with filing dates only days apart could have widely-varying expiration dates. *Id.* Thus, “[l]ooking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting.” *Id.* at 1216. Such a rule “guarantees a stable benchmark that preserves the public’s right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires.” *Id.*

In view of the reasoning and holding of *Gilead*, summary judgment is unavoidable here. Although the patents at issue in *Gilead*, unlike here, were not technically part of the same patent family, the Federal Circuit placed no significance on that fact, which was irrelevant to its reasoning. *Id.* at 1214–17. Nor did the court make any finding that the manner in which the

³ Because patent term was typically determined by issue date prior to the changes effecting patent term enacted in 1994, issue date once served as a stand-in for a patent’s expiration date. *Gilead*, 753 F.3d at 1215; *see also id.* at 1211 (discussing changes to patent term that became effective June 8, 1995). Because the '444 patent was filed after those changes to patent term became effective, its issue date cannot serve as a stand-in for its expiration date, which controls.

Gilead patentee had obtained its patents was improper, or that it had engaged in any “gamesmanship” in crafting a separate chain of applications. *Id.* Put simply, under *Gilead* it makes no difference *why* the patents have different expiration dates—so long as one patent survives the expiration of the other. Ultimately, the court concluded that “[i]n cases where such obviousness-type double patenting is present, a terminal disclaimer”—which officially abandons the extra patent term otherwise provided by the later-expiring patent—“can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent. That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent’s term expires.” *Id.* at 1217. So too here. To hold otherwise in this case would “violate[] the public’s right to use the invention claimed in the [’444] patent and all obvious variants of it after the [’444] patent expire[d].” *Id.* at 1214.

Gilead is indistinguishable. The ’444 patent expired in 2011, but the ’471 patent expires in 2018. Facts 5, 6. Thus, the ’444 patent is a proper double-patenting reference against, and serves to render invalid, the ’471 patent as a matter of law.

C. Janssen Cannot Claim Refuge In The Safe Harbor Of § 121

There is a limited safe harbor when double-patenting occurs as a result of the Patent Office’s requirements, but that safe harbor is inapplicable here and cannot save the ’471 patent. The third sentence of 35 U.S.C. § 121 provides:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121; *see also Amgen*, 580 F.3d at 1353. “In effect, the third sentence of § 121 shields patents that issue on applications filed as a result of a restriction requirement from double patenting invalidation.” *Id.* at 1350. The courts apply “a strict test” for application of section 121, “[g]iven the potential windfall [a] patent term extension could provide to a patentee.” *G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349, 1354 (Fed. Cir. 2015) (citing *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003)). Janssen is not entitled to the protection of § 121’s safe harbor provision as a matter of law.

As a threshold matter, Janssen’s ’471 patent simply fails to meet the express requirement to invoke § 121. In Patent Office practice, there are different types of continuing applications, including “divisional,” “continuation,” and “continuation-in-part” applications, each having different legal requirements and effects. By its express terms, § 121 is available only to applications filed as “divisional” applications, and is unavailable for applications filed as “continuation” or “continuation-in-part” applications. *G.D. Searle*, 790 F.3d at 1355; *Amgen*, 580 F.3d at 1352–53; *Pfizer*, 518 F.3d at 1362. Janssen filed the ’471 patent application as a “continuation-in-part” application on February 4, 1994, and filed the ’444 patent application as a “divisional” application on January 8, 2001. Facts 5, 6. As discussed further below, that fact alone prohibits Janssen from now seeking protection under the safe harbor.

Even if Janssen could satisfy the statutory threshold, the safe harbor cannot apply for a second substantive reason—Janssen cannot establish the requisite “consonance” to the restriction requirement that resulted in the issuance of separate patents. *Gerber Garment Tech, Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990); *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1377 (Fed. Cir. 2013). If the Patent Office believes that an application contains claims to independent, distinct inventions, it will issue what is known as a “restriction”

requirement requiring the patent applicant to elect one group of claims to one of the inventions, leaving the other group or groups of claims to the other inventions to be further prosecuted in separate applications. “Consonance requires that the line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction requirement be maintained.” *Gerber Garment*, 916 F.2d at 688. As such, the divisional “may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application.” *Id.*; *see also St. Jude Medical*, 729 F.3d at 1377.

In 1993, during the prosecution of one of Janssen’s early parent applications to the ’471 and ’444 patents, the Patent Office issued a restriction requirement, forcing Janssen to elect to prosecute in that particular application only one group of claims out of several groups. Fact 10. The first group identified by the examiner, so-called “Group I,” was drawn to claims reciting “chimeric antibodies.” Janssen could (and did) prosecute the non-elected groups of claims in separate, continuing patent applications. Facts 10, 11. In particular, the ’471 patent claims “chimeric antibodies,” the subject of Group I of the restriction requirement of the parent application; but, the ’444 patent *also* claims “chimeric antibodies” and is therefore directed to the same subject matter of Group I. Facts 10–12. Because Janssen has claims to the same restricted invention in the two patents, it has not maintained the line of demarcation of the restriction requirement and thus fails the “consonance” test. Thus, for this additional reason, the safe harbor of § 121 is unavailable to Janssen.

IV. The ’471 Patent Is Also Invalid In View Of The ’195 And ’272 Patents Under The Doctrine Of Obviousness-Type Double Patenting

As an independent ground for summary judgment, the ’471 patent is also invalid under the doctrine of obviousness-type double patenting in view of two other already-expired patents that Janssen owns. The ’195 patent expired on December 16, 2014, and the ’272 patent expired

on August 12, 2014. Facts 7, 8. Both recite claims that are not patentably distinct from the '471 claims as a matter of law. Summary judgment of invalidity could be granted on either of these alternative grounds as well.

Claim 6 of the '195 patent recites a “method for treating rheumatoid arthritis” by administering infliximab, i.e., the “chimeric anti-TNF anti[b]ody cA2.” Fact 16. Claim 7 of the '272 patent recites a “method for treating TNF α -mediated Crohn’s disease,” an autoimmune disorder, by administering infliximab: “chimeric anti-TNF antibody cA2.” Fact 17. Because the earlier-expiring '272 and '195 patents’ method claims disclose the use of the infliximab composition, they anticipate (or at the very least render obvious) the '471 patent’s later-expiring claims to the infliximab antibody itself.

In the Patent Office, Janssen is attempting to avoid invalidity through the rarely-applied “two-way” test for obviousness-type double patenting. But there is a strong presumption in favor of the “one-way” test, in which the validity of *only* the *asserted claims* are evaluated against the reference patent claims. *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009). Under the two-way test, by contrast, the validity of the *reference patent claims* are *also* evaluated against the asserted claims—that is, the obviousness of *both* sets of claims are evaluated against each other. But a two-way test applies “*only* in the ‘unusual circumstance’ where ‘the PTO is *solely responsible* for the delay in causing the second-filed application to issue prior to the first.’” *Hubbell*, 709 F.3d at 1149 (emphasis added, internal citation omitted). “The determination of whether a one-way or two-way analysis applies is . . . a question of law . . .” *Bassell Poliolefine*, 547 F.3d at 1375–76.

Janssen cannot overcome the presumption favoring the one-way test—as the PTO examiner found—because the Patent Office plainly was not “*solely*” responsible for the timing

producing the double-patenting problems. Fact 30. Janssen was at least *partially* responsible for the massive delay in the issuance of the '471 patent. *See id.* For example, Janssen requested and received at least *six* extensions of time. Fact 38. Moreover, although the Patent Office repeatedly indicated that there was allowable subject matter—which could have resulted in immediate issuance—Janssen further delayed prosecution by submitting amendments and even new claims drawn to non-elected subject matter, resulting in years and years of delay. Facts 31–37; *see also* Fact 30.

In any event, even if the two-way test applies, Janssen cannot avoid double patenting. A “claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use.” *Sun Pharm.*, 611 F.3d at 1387 (citation omitted). That is the case here. The '471 patent claims recite the composition infliximab, and the specification of the '471, '195 and '272 patents all disclose the utility of infliximab to treat various conditions including rheumatoid arthritis and Crohn’s disease. Fact 29. Thus, the claims of the '195 and '272 patents (methods of using infliximab) are not patentably distinct over the claims of the '471 patent (infliximab antibody) and the express disclosure of the utility of infliximab to treat rheumatoid arthritis and Crohn’s disease.

Finally, Janssen cannot rely on the safe harbor, because (as discussed above) it filed its '471 application as a “continuation-in-part” application on February 4, 1994, rather than a “divisional” application filed as a result of a restriction requirement as required to invoke the safe harbor. Recognizing this problem, Janssen is attempting to convert its “continuation-in-part” application into a “divisional” through maneuverings before the Patent Office. But as of now, the application remains a “continuation-in-part.” Even Janssen in its papers filed with this

Court acknowledges that the amendments to the specification of the '471 patent "will not take effect outside of the PTO until the reexamination proceedings are complete." Fact 39.

In any event, even if that amendment were to take effect in the *future*, it would not save the '471 patent. The safe harbor statute not only requires a divisional (as opposed to a continuation-in-part) application to be filed as a result of a restriction requirement, it further requires that this "divisional application [be] filed *before* the issuance of the patent on the other application." 35 U.S.C. § 121 (emphasis added). As an historical fact, the '471 application was not filed as a "divisional" as a result of a restriction requirement, not did Janssen amend its continuation-in-part to a divisional "*before*" the issuance of the '195 and '272 patents.⁴ Facts 5, 7, 8. *See id.*; Manual of Patent Examining Procedure § 804.01 (noting § 121 requires that "the *divisional application* is filed before the issuance of the patent." (emphasis added)); Federico, P. J., *Commentary on the New Patent Act* in 75 *J. Pat. & Trademark Off. Soc'y* 161, 196 (1993) (commenting that "if two or more *divisional applications* are filed as a result of a multiple requirement for restriction, they each must be filed before the original application is patented in order to obtain the benefit of this provision [35 U.S.C. § 121]."). Accordingly, the safe harbor protection of § 121 does not apply.

CONCLUSION

For the reasons above, the asserted claims of the '471 patent are invalid under the doctrine of obviousness-type double patenting in view of any one of the '444, '195 and '272 patents, and the Court should grant summary judgment to the Defendants.

* * *

⁴ The '471 patent application was filed as a "continuation-in-part" and remained a continuation-in-part when it issued, years after the '195 and '272 patents issued. Fact 5, 7, 8. Therefore, even if the '471 patent is called a divisional sometime in the future, it would still not have been filed as a divisional prior to the issuance of the reference patents.

Dated: February 19, 2016

Respectfully submitted,

Celltrion Healthcare Co., Ltd., Celltrion, Inc. and
Hospira Inc.

By their attorneys,

/s/Andrea L. Martin

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on February 19, 2016.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

EXHIBIT 10

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BEFORE THE HONORABLE MARK L. WOLF
UNITED STATES DISTRICT JUDGE

MOTTON HEARTING

August 17, 2016
1:05 p.m.

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Boston, Massachusetts 02210

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1 P R O C E E D I N G S

2 THE COURT: Good afternoon. Would counsel please
3 identify themselves for the Court and for the record.

4 MR. DISKANT: Greg Diskant for the plaintiffs, along
5 with Irena Royzman, Barbara Mullin. We've got a substitute
6 back here, Nathan Monroe-Yavneh, and our tech guy.

7 THE COURT: Okay.

8 MR. HURST: Jim Hurst on behalf of defendants. Client
9 representatives are here as well, Jeff Myers and David Kim.
01:05 10 And I'll let the others introduce themselves.

11 MS. CUTRI: Good morning, Your Honor. Elizabeth Cutri
12 of Kirkland & Ellis.

13 MR. KLEIN: Good morning, Your Honor. Chuck Klein of
14 Winston & Strawn.

15 MR. HOANG: Good afternoon. Dan Hoang, Winston
16 Strawn.

17 MS. MARTIN: Good afternoon, Your Honor. Andrea
18 Martin from Burns & Levinson.

19 MR. KELLY: Good afternoon, Your Honor. Dennis Kelly
01:05 20 Burns & Levinson.

21 THE COURT: Okay. I have not heard from you since we
22 recessed yesterday. So I assume there's -- maybe the two
23 people in the front row there would go out of the courtroom.
24 Right there, the two who were just talking. I can't do this.
25 I've got a dozen lawyers here. You're welcome to talk in the

1 hallway. You're not welcome to talk in the courtroom. You're
2 sitting right in front of me. It's extremely distracting. You
3 can stay if you'll heed that admonition, please.

4 I'm sorry. Counsel were rising.

5 MR. HURST: Discussions did occur. I know both
6 parties were doing their best to see if they could reach some
7 common agreement here, and it was, unfortunately, unsuccessful.
8 That's my understanding, Your Honor.

9 MR. DISKANT: That's my understanding as well, Your
01:06 10 Honor. I know the parties are committed to continuing to talk
11 to each other, and I'm sure they will do that.

12 THE COURT: Okay. I am prepared to give you my
13 decision on the '471 patent obviousness double patenting motion
14 for summary judgment. I'm not yet prepared to give you my
15 decision with regard to the reexamination motion. I expect
16 I'll do that tomorrow. After I explain my reasoning for
17 allowing the defendants' motion based on obviousness double
18 patenting, we'll move to the argument on the '083 patent.

19 All right. I'm deciding this matter orally, as I said
01:08 20 yesterday. There's urgency to it under this new statutory
21 regime for biosimilar drugs. I am immersed in this and have
22 your arguments vividly in mind. Although I'm deciding this
23 orally, I hope it will be evident that I'm not deciding it
24 casually. The transcript will be the immediate record of the
25 decision. I may, very well may convert the transcript at some

1 point into a more formal memorandum and order.

2 As I said, the defendants' motion for summary judgment
3 on the '471 patent based on obviousness double patenting,
4 docket number 127, is hereby allowed. The parties agree that
5 no material facts are in dispute. The issue is solely a
6 question of law. Therefore, this issue is ripe for resolution
7 on the defendants' motion for summary judgment.

8 With regard to background, the plaintiffs, Janssen
9 Biotech, Inc. and New York University, who are sometimes
01:09 10 collectively called Janssen, are the holders of patents related
11 to a biologic medication called Remicade, which is based on an
12 antibody called infliximab.

13 Plaintiffs allege that defendants Celltrion and
14 Hospira have infringed these patents by filing an abbreviated
15 Biologic License Application for a product that is "biosimilar"
16 to Remicade. Two patents are at issue in this motion for
17 summary judgment based on obviousness-type double patenting.
18 They are U.S. Patent Number 6,284,471, which I'll refer to as
19 the '471 patent or the '471, and U.S. Patent Number 6,790,444,
01:10 20 to which I will refer as the '444 patent or the '444. The '471
21 patent covers a genus, or group, of compounds that includes
22 infliximab. The '444 patent is for the infliximab antibody
23 specifically.

24 Plaintiffs concede that the '444 patent claims are not
25 patentably distinct from the '471 patent claims. Both patents

1 are based on an application filed in 1991, which is sometimes
2 called the "priority application." The priority date for each
3 patent is 1991.

4 The '471 patent was filed in 1994 and issued on
5 September 4, 2001. If it stood alone, it would expire on
6 September 4, 2018 because it was filed before the 1995
7 effective date of the law altering patent terms, the Uruguay
8 Round Agreements Act, or URAA, which the defendant at least
9 sometimes called the GATT.

01:12 10 The statute is codified at 35 U.S.C. Section 154, most
11 pertinently at Section 154(c)(1). The URAA provides protection
12 for 20 years from the date of the original, priority
13 application or 17 years after issuance, whichever is longer,
14 for applications filed before 1995. Therefore, if the '471
15 patent stood alone, it would expire in 2018. However, for
16 applications filed after 1995, patent protection extends for 20
17 years after the date the original, priority application was
18 filed. The application for the '444 patent was filed in 2001,
19 after the 1995 effective date of the URAA, and was issued in
01:12 20 2004. As it was based on a 1991 priority application, it
21 expired 20 years later, in 2011.

22 In what the parties call the defendants' *Gilead*
23 motion, the defendants seek summary judgment of invalidity on
24 Claims 1, 3, 5, 6 and 7 of the '471 patent for obviousness-type
25 double patenting based on the '444 patent. The only question

1 presented by the motion is whether, in view of the Federal
2 Circuit's decision in *Gilead Sciences, Inc. v. Natco Pharma*
3 *Limited*, 753 F.3d 1278, a 2014 decision, the earlier-expiring
4 '444 patent should be held to be a double patenting reference
5 that invalidates the '471 patent. I find that it is such a
6 reference, and therefore the '471 patent is invalid.

7 *Gilead* involved two patents based on applications
8 filed after 1995. Therefore, it did not implicate the
9 provision of the URAA that provides patent protection for at
01:14 10 least 17 years after issuance if the application for a patent
11 at issue was filed before 1995. As this case is factually
12 different than *Gilead*, *Gilead* is not binding precedent for the
13 purpose of deciding this case. I find, however, that in
14 enacting the URAA, Congress and the President did not intend to
15 alter the judicially-created doctrine of obviousness double
16 patenting or restrict the power of the courts to apply it to
17 patents resulting from applications filed before 1995.

18 I also find that the Federal Circuit would apply the
19 *Gilead* ruling to the circumstances of this case and again find
01:15 20 that a later-issued but earlier-expiring patent can serve as a
21 reference that renders an earlier-issued but later-expiring
22 patent invalid for obviousness double patenting. In *Gilead*,
23 253 F.3d at 1214, the Federal Circuit wrote, "It is a bedrock
24 principle of our patent system that when a patent expires, the
25 public is free to use not only the same invention claimed in

1 the expired patent but also obvious or patentably indistinct
2 modifications of that invention." It then cites *In re Longi*
3 for the proposition that the public should be able to act on
4 the assumption that upon the expiration of a patent, it will be
5 free to use not only the invention claimed in the patent but
6 also any modifications or variants thereof which would have
7 been obvious to those of ordinary skill in the art at the time
8 the invention was made.

9 "The double patenting doctrine has always been
01:16 10 implemented to effectively uphold that principle," said the
11 Federal Circuit. The plaintiff acknowledges that the invention
12 claimed in the '471 patent is obvious or patentably
13 indistinct -- I'm sorry -- is an obvious or patentably
14 indistinct modification of the invention claimed in the '444
15 patent.

16 In *Gilead* at 1210, the Federal Circuit explained that
17 the obviousness-type double patenting doctrine prohibits an
18 inventor from extending his right to exclude through claims in
19 a later-expiring patent that are not patentably distinct from
01:17 20 claims of the inventor's earlier-expiring patent. The Federal
21 Circuit noted at page 1212 that Federal Courts had applied this
22 principle for over a century.

23 In *Gilead*, at 1216, the Federal Circuit essentially
24 rejected plaintiffs' argument here that the URAA manifests a
25 statutory intent to provide patents emerging from applications

1 filed before 1995 with at least 17 years' protection despite
2 the otherwise applicable judicial doctrine of obviousness
3 double patenting. The URAA is silent on this issue. It does
4 not state that pre-URAA patents will always have 17 years'
5 protection, nor does it reference the doctrine of obviousness
6 double patenting.

7 Generally, the Supreme Court "presumes that
8 legislatures act with case law in mind," as the Supreme Court
9 wrote in *Abuelhawa v. United States*, 129 Supreme Court 2102 at
01:19 10 2106, a 2009 decision. The Supreme Court made a similar
11 statement in *Miles v. Apex*, 111 Supreme Court 317 at 325.
12 Consistent with this well-established canon, the Federal
13 Circuit wrote in *Gilead* at 1216, "Congress could not have
14 intended to inject the potential to disturb the consistent
15 application of the doctrine of double patenting by passing the
16 URAA."

17 In *Gilead* at 1215, the Federal Circuit stated that,
18 "The primary ill avoided by enforcement of the double patenting
19 doctrine is a restriction on the public's freedom to use the
01:19 20 invention claimed in a patent and all obvious modifications
21 after that patent expired." Therefore, the Federal Circuit
22 held, at 1217, that an earlier-expiring patent can qualify as
23 an obviousness-type double patenting reference for a
24 later-expiring patent under the circumstances here. In
25 reaching this conclusion in reversing the decision of the

1 District Court, the Federal Circuit at 1211 stated that the
2 District Court had mistakenly relied on the reasoning of two
3 pre-*Gilead* decisions involving, as this case does, pre- and
4 post-URAA patents. There are two cases on which the plaintiff
5 relies here. *Abbott Labs*, 2011 Westlaw 1897322, a 2011
6 Delaware decision, and *Brigham and Women's Hospital*, 761 F.
7 Supp. 2d 210, another 2011 District of Delaware decision.

8 In *Gilead*, the Court noted at 1211 in footnote 2, that
9 in *Ex-Parte Pfizer*, the Board of Patent Appeals, on facts
01:21 10 analogous to the facts of the instant case, found that the
11 later-issued but earlier-expiring patent invalidated an
12 earlier-issued later-expiring patent under the doctrine of
13 obviousness double patenting because the later-expiring patent,
14 in the Board's opinion, would impermissibly block the public
15 from practicing the invention and obvious derivations thereof
16 disclosed in the patents that expired first.

17 This reference to *Pfizer*, among all of the reasoning
18 in *Gilead*, indicates to me that the Federal Circuit would in
19 this case find the '471 patent obvious and invalid in view of
01:22 20 the expired '444 patent. If the plaintiffs' position were
21 correct, the public would be prevented from practicing the
22 expired '444 patent and an obvious patentably indistinct
23 variation of it. This would violate the bedrock principle that
24 when a patent expires, the public is free to use the invention
25 claimed and obvious variations of it, which is at the heart of

1 the obviousness double patenting doctrine, which the Federal
2 Circuit has found to be unaltered by the URAA.

3 The obviousness double patenting document was well
4 established when plaintiff applied for and accepted the '444
5 patent, which it knew would expire in 2011. The plaintiff
6 decided to take at least the risk that the '471 would be deemed
7 invalid when the '444 expired.

8 Infliximab was covered by the '471 genus patent, which
9 plaintiff obtained, and by the '444 specious patent that
01:24 10 specifically claimed that antibody. As plaintiffs' counsel
11 acknowledged at the August 16, 2016 hearing, such narrower
12 patents are generally acquired to protect against claims of
13 invalidity or infringement. That risk was real here as the PTO
14 has, in the pending reexamination, found that the '471 is
15 obvious and invalid in view of two other patents plaintiffs
16 held, the '195 and the '272.

17 Although not material to the analysis, I note that the
18 plaintiff had a significant incentive to try to avoid the risk
19 of invalidity of the '471 patent by obtaining the '444 patent
01:25 20 as the parties have agreed in informing the court that Remicade
21 has generated sales of more than \$4 billion a year.

22 In *AbbVie*, 764 F.3d 1366 at 1374, a 2014 Federal
23 Circuit case, the Federal Circuit confirmed that the doctrine
24 of obviousness-type double patenting continues to apply where
25 two patents that claim the same invention have different

1 expiration dates. It reiterated the ruling of *Gilead* at page
2 1379 of *AbbVie*, that if the later-expiring patent is merely an
3 obvious variation of the invention disclosed and claimed in the
4 reference patent, the later-expiring patent is invalid for
5 obviousness-type double patenting.

6 I find that this reasoning is equally applicable to
7 the facts of this case. More specifically, I hold that the
8 expired '444 patent is a reference for the '471 patent. The
9 '471 patent is not patentably distinct from the '444 patent,
01:26 10 therefore the '471 patent is invalid.

11 I note that this conclusion is consistent with what is
12 evidently the only other decision on comparable facts. *MLC*
13 *Intellectual Property*, 2016 Westlaw, 41920009, a Northern
14 District of California case, decided on August 9, 2006, in
15 addressing the issues presented here, briefly on page 3 in note
16 4.

17 Accordingly, as I said, the defendants' motion for
18 summary judgment finding the '471 patent invalid, docket number
19 127, is hereby allowed.

01:27 20 So have the parties discussed who should go first with
21 regard to the claim construction of the '083?

22 MR. DISKANT: Yes, Your Honor. We agreed that, since
23 we are the plaintiffs, we would go first on claim construction.
24 And my colleague Irena Royzman will present our argument.

25 THE COURT: Okay.

1 MS. ROYZMAN: Your Honor --

2 THE COURT: Hold on for just a second. I'm waiting
3 for your audience to go.

4 Many people just left the courtroom. Somebody should
5 watch what happens to the stock of whoever's stock is affected
6 by this.

7 Go ahead. Here, I have some questions. You don't
8 have to answer them necessarily in this order, but you should
9 address them at some point. In 2000 in *Biogen v. Berlex*, 113
01:29 10 F. Supp. 2d 77 at 95 to 96, I stated what were then at least
11 the standards for *Markman* hearings and proper procedures. I
12 wonder if the parties have them in mind, whether you agree that
13 that's still a reliable statement of the standards.

14 MR. HURST: Can you say that page number again, Your
15 Honor?

16 THE COURT: Sure. 95 to 96. Maybe that will take you
17 a while to get. But there are some cases that I found
18 particularly significant with regard to claim construction.
19 *Phillips*, 415 F.3d 1303 at 1312 to 19, *Renishaw*, 158 F.3d 1243
01:30 20 to 1248 to 50. *Comark*, 156 F.3d 1182 at 1186 to 87, and
21 *Thorner*, 669 F.3d 1362 at 1365 to 67.

22 Those are cases that the parties cited. Are they
23 still good law?

24 MS. ROYZMAN: *Thorner* is good law.

25 THE COURT: You want to stand up.

1 MS. ROYZMAN: I'm sorry, Your Honor. I'm actually
2 going to do the presentation from the podium, not to have to
3 bend over the microphone. But *Thorner* is good law, *Renishaw* is
4 good law. I think Your Honor cited *Phillips*. *Phillips* is an
5 en banc decision that sets forth the principles for claim
6 construction. Those are still good law. You start with the
7 claims. You look at the spec, prosecution history.

8 THE COURT: Okay. What about *Comark*?

9 MS. ROYZMAN: I believe *Comark* is as well, but I would
01:31 10 have to check back.

11 THE COURT: Mr. Hurst?

12 MR. HURST: I would have to check as well, Your Honor.
13 I believe that I agree with *Thorner*, *Phillips* and *Renishaw*.
14 And I just looked at the *Renishaw* quote, for instance. I
15 believe that to still be the law, and they probably still say
16 the same type of thing.

17 THE COURT: All right. *Comark*, one of the legions on
18 each side can look at in the course of the argument.

19 Then this is of some significance to me. As I
01:32 20 understand it, in this *Markman* motion, I'm asked to construe a
21 term in Claim 1, "cell culture media." I'm not asked to define
22 the scope of the invention defined by all of Claim 1, which
23 includes language in addition to the term "cell culture media."
24 Is that right, Mr. Hurst?

25 MR. HURST: That is correct, Your Honor.

1 THE COURT: Is that also the plaintiffs'
2 understanding?

3 MS. ROYZMAN: Yes, it is, Your Honor.

4 MR. HURST: May I just qualify just a little bit? I
5 think maybe I answered too quickly. By defining the meaning of
6 that term "cell culture media," you help to define the scope of
7 the invention.

8 THE COURT: It helps to define it. I'm just being
9 asked to define the term, not the scope of the invention
01:33 10 claimed in Claim 1.

11 MR. HURST: They are related, but what you say is
12 correct.

13 THE COURT: All right. Then as far as I can tell,
14 there was one technical dictionary submitted by the plaintiff
15 as docket number 149-3, it's Exhibit 2, that defines "culture
16 medium" as any medium that is designed to support the growth or
17 maintenance of a culture. That's the Oxford Dictionary of
18 Biochemistry and Molecular Biology, revised edition. Are there
19 any other technical dictionaries in the record that I should
01:33 20 look at, or are there any other technical dictionaries in the
21 record?

22 MS. ROYZMAN: Your Honor, I'd have to look back. I am
23 not sure there are other technical dictionaries, but I think
24 the ordinary and plain meaning --

25 THE COURT: Okay. I'm going to get to that because

1 you did give me some dictionaries.

2 MS. ROYZMAN: Yes. But I think the ordinary and plain
3 meaning isn't disputed here.

4 THE COURT: Well, we'll see, but I'm asking you, are
5 there any other technical dictionaries?

6 MS. ROYZMAN: I have to check back.

7 THE COURT: All right. Did the defendant give me any
8 technical dictionaries?

9 MR. HURST: I do not think that we did.

01:34 10 THE COURT: All right. And then there's a whole set
11 of exhibits the plaintiff gave me as part of 149. Some of them
12 are treatises. But it wasn't clear to me what the pertinent
13 parts of the treatises were.

14 Are you going to address that, or should I just ignore
15 them in my analysis?

16 MS. ROYZMAN: I think, to the extent it's significant,
17 I'll address them in the presentation, Your Honor.

18 THE COURT: And then I have extrinsic expert testimony
19 from the defendant. I think not from the plaintiff, right?

01:35 20 MS. ROYZMAN: Not exactly, Your Honor. So what
21 happened was we didn't think extrinsic testimony was necessary
22 but then in the opening brief, as Your Honor just noted,
23 defendants put in a declaration from a Dr. Nikos Panayotatos.
24 And now in our answering brief, we put in a responsive
25 declaration. We still don't think expert testimony is truly

1 needed here, given the issues.

2 THE COURT: Thank you for that clarification, because
3 I'll tell you, I'm skeptical about whether I should give much
4 or any weight to the extrinsic expert testimony. *Phillips*
5 cautions, 415, F.3d at 1318, that such testimony may be biased
6 because it was prepared for litigation, and it wasn't available
7 to persons skilled in the art previously.

8 So in any event, that kind of expert testimony can't
9 alter the construction that comes -- that's communicated
01:36 10 clearly by the intrinsic record, the claims, the specification,
11 the prosecution history. So you might want to keep that in
12 mind when you make your argument. I'm skeptical about the
13 expert testimony, and there's a Federal Judicial Center
14 publication, Anatomy of a Patent Case, second edition in 2012
15 at pages 101 to 102, essentially, recapitulates the admonitions
16 in *Phillips*.

17 All right. Then I expect you have this in your
18 slides, but I want to make sure I've got it clearly. Just one
19 minute, please. As I understand it, Janssen's proposed
01:38 20 construction of the term "cell culture media" is that I should
21 give it its plain and ordinary meaning or construe it to mean a
22 nutritive media for culturing cells. Is that right?

23 MS. ROYZMAN: Yes, which is its plain and ordinary
24 meaning, so no construction, or just the plain and ordinary
25 meaning.

1 THE COURT: All right. As I understand it, the
2 defendants' proposed construction is "Chemically defined media,
3 i.e. media compositions containing only known chemical
4 compounds and are free of all proteins, even those not of
5 animal origin, such as recombinant proteins, optimized for
6 biopharmaceutical production." Is that correct?

7 MR. HURST: That's correct, Your Honor.

8 THE COURT: Mr. Hurst, maybe this is a preview of
9 coming attractions, but is it the defendants' position that the
01:39 10 plaintiff was either its own lexicographer or disavowed the
11 ordinary meaning of "cell culture media"?

12 MR. HURST: Both, Your Honor.

13 THE COURT: Both? My understanding from the *Genentech*
14 decision as well as the pertinent part of *Chisum* is that
15 "'Comprising' means in effect that the invention necessarily
16 includes but is not limited to." Is that the plaintiffs'
17 position?

18 MS. ROYZMAN: Yes, it is, Your Honor.

19 THE COURT: Does the defendant disagree with that?

01:40 20 MR. HURST: That is normally how you would construe
21 the word comprising, but there are obviously cases out there
22 that give it a more limited scope.

23 THE COURT: What cases are those?

24 MR. HURST: For instance, *Gillette*.

25 THE COURT: Is this cited in your brief?

1 MR. HURST: It is, Your Honor. 405 F.3d 1367.

2 THE COURT: Hold on a second. Is there another one?

3 MR. HURST: Gillette cites *Spectrum International* at
4 164 F.3d 1379. That's an "at" cite, at 1379.

5 THE COURT: Okay. Thank you. Just out of curiosity,
6 when does the '083 expire?

7 MS. ROYZMAN: I don't remember the exact date, Your
8 Honor. It's sometime in the 2020s.

9 THE COURT: All right. You can tell me later. Maybe
01:42 10 Mr. Hurst knows.

11 MR. HURST: I don't, Your Honor.

12 THE COURT: I think this has some practical
13 significance. It's \$4 billion a year. I want to know what the
14 stakes are in the decision I'm going to make, and I would think
15 if you're talking to each other about a businesslike
16 resolution, you'd want to know what turns on this issue.

17 MR. HURST: I should, and I know it's way off to the
18 future into the 2020s. I'm sure somebody told me the date.
19 I'm sure I read it and knew it. It's not coming to me.

01:43 20 THE COURT: Well, again, somebody can find it, I'm
21 sure. Ms. Royzman, about how long do you think you want for
22 your presentation?

23 MS. ROYZMAN: Little over an hour or about an hour.

24 THE COURT: All right. I'm pretty familiar with this.
25 Well, I'm very familiar with this and accept your arguments.

1 All of your arguments are very helpful. They're very good,
2 very helpful. I told you I'm inclined to rule in your favor.
3 So why don't you present this as efficiently as you can, and
4 then I'll give you a chance to respond, if necessary.

5 MS. ROYZMAN: Okay. May I finish?

6 MR. HURST: 2027, Your Honor.

7 MS. ROYZMAN: Thank you very much.

8 THE COURT: So 11 years, \$4 billion a year, at present
9 rates --

01:44 10 MR. HURST: Not a small amount of money.

11 THE COURT: \$44 billion.

12 MS. ROYZMAN: Okay. Your Honor, so I will definitely
13 try to be as efficient as possible, and to the extent certain
14 material is already familiar, just move me along.

15 THE COURT: Okay.

16 MS. ROYZMAN: Thank you.

17 THE COURT: Do you have some slides for me?

18 MS. ROYZMAN: I sure do.

19 THE COURT: What are we on, E? We'll make these
01:44 20 Exhibit E of these hearings.

21 You may proceed.

22 MS. ROYZMAN: Thank you, Your Honor. So with
23 recombinant DNA technology, in the '70s it became possible to
24 produce biopharmaceuticals in cells. But in order to produce
25 biopharmaceuticals in cells, you of course need to be able to

1 grow and maintain cells in vitro, and that's where cell culture
2 comes in. So cell culture media makes it possible to grow and
3 maintain cells. It's a nutritive media, and that's what cell
4 culture media is, and that's what the '083 patent is about.

5 And cell culture media is essential to the drug.
6 Without cell culture media, there is no drug, and the cell
7 culture media is also important in that it influences the
8 property of the drug and its physical characteristics as a
9 result of what -- the nutrients that the cells are taking in.

01:46 10 Okay. So what's the claim construction issue here?
11 It's the definition of the term "cell culture media" as used in
12 the claims of the '083 patent. And Janssen relies on the plain
13 and ordinary meaning. Celltrion first argued that the term
14 includes only a specific subset of cell culture media,
15 chemically defined media. And they provided the definition of
16 that that Your Honor read.

17 And during briefing, Celltrion recognized that their
18 initial construction was truly untenable because it
19 contradicted the intrinsic evidence, it contradicted the
01:47 20 claims, it contradicted the specification, and so Celltrion
21 proposed an alternative construction, a different subset of
22 cell culture media, media that's free of all proteins.

23 THE COURT: As well as being chemically defined?

24 MS. ROYZMAN: No, no. So the alternative construction
25 is just "free of all proteins," so they abandoned "chemically

1 defined" in the alternative construction just because it is
2 truly untenable in view of the intrinsic evidence.

3 THE COURT: Wait, wait, wait.

4 MS. ROYZMAN: Your Honor, it's in the answering brief.

5 THE COURT: Hold on just one second.

6 MS. ROYZMAN: Absolutely.

7 THE COURT: All right. I had just asked Mr. Hurst if
8 the defendants' proposed construction was "Chemically defined
9 media, i.e. media compositions containing only chemical
01:49 10 compounds and are free of all proteins even those not of animal
11 origin such as recombinant proteins optimized for
12 biopharmaceutical production deduction." I think he said that
13 was it.

14 MR. HURST: That's our primary position, there's an
15 alternative way to get to the end zone. Although our primary
16 position is "chemically defined," Your Honor.

17 THE COURT: Doesn't sound like they've abandoned it.

18 MR. HURST: We have not, Your Honor.

19 MS. ROYZMAN: Well, through the alternative
01:49 20 construction, they've abandoned "chemically defined." Neither
21 of Celltrion's construction has any support in the intrinsic
22 evidence.

23 THE COURT: Hold on just a second. So the defendant
24 has two proposed constructions?

25 MR. HURST: We have an alternative proposal to

1 address. One of the arguments that Janssen has raised, Your
2 Honor --

3 THE COURT: And the alternative is what.

4 MR. HURST: The alternative is "nutritive media free
5 of all proteins for culturing eukaryotic cells." It's on page
6 4 of our reply brief.

7 THE COURT: Say it again, please.

8 MR. HURST: Sure. "Nutritive media free of all
9 proteins for culturing eukaryotic cells." Essentially "free of
01:51 10 all proteins." That's the key point.

11 THE COURT: Okay.

12 MS. ROYZMAN: Your Honor, so turning to the '083
13 patent, so the '083 patent is assigned to Centocor, which is
14 now Janssen. And Centocor and Janssen are leaders in the
15 production of biopharmaceuticals of antibodies. The relevant
16 date for this work is 2004, and that's highlighted here. Dr.
17 Epstein is the lead inventor, and he's dedicated decades to
18 developing cell culture media. And the title of the patent is,
19 "Chemically defined media compositions," and we'll discuss what
01:52 20 that is.

21 So the backdrop for the invention is that there was a
22 concern at the time about the contamination of conventional
23 eukaryotic cell culture media, a type of cell culture media,
24 with adventitious particles, and such particles, basically
25 adventitious particles, particles that go along for the ride,

1 can be bacteria, viruses or prion particles.

2 THE COURT: And can give you mad cow disease or
3 something like that.

4 MS. ROYZMAN: Exactly. Prion particles are what do
5 that. And that's what this says. It says, "Such contaminants
6 in a biopharmaceutical are capable of causing patient
7 infections and disease, such as mad cow."

8 And still in the background, the patent explains that
9 adventitious particle contamination --

01:53 10 THE COURT: What does "adventitious" mean?

11 MS. ROYZMAN: The way I understand it is basically
12 particles that go along for the ride. And so adventitious
13 particle contamination can be avoided by culturing eukaryotic
14 cells in animal component free cell culture media. That's
15 again a type of cell culture media, and it's animal component
16 free. And what that means is exactly what it sounds like.
17 It's free of animal components.

18 THE COURT: Means there's nothing there to go along
19 for the ride?

01:53 20 MS. ROYZMAN: Yes, yes. Then the patent states again
21 in the background that, "Ideally, such media are chemically
22 defined such that the media compositions contain only known
23 chemical compounds and are free of all proteins, even those not
24 of animal origin, such as recombinant proteins."

25 So why does it say that or why does it express this

1 ideal? So chemically defined media, media where the media
2 composition contains only known chemical compounds, that's
3 advantageous because you basically reduce variability from
4 batch to batch because you know exactly what you're putting in.
5 So there's an advantage to that, and that represents an ideal.
6 Then it's also ideally free of all proteins, even those not of
7 animal origin, such as recombinant proteins.

8 So "free of all proteins" means no proteins of any
9 kind, no plant proteins, no animal proteins, no proteins that
01:54 10 are recombinant, meaning made by man in a dish. And why is
11 that advantageous? That has benefits in terms of -- well,
12 proteins can be expensive. It's also advantageous because, you
13 know, if you're trying to purify your antibody and you've got
14 other proteins in there, it's a little more complicated, so
15 there are advantages. The patent says this represents an
16 ideal, so an ideal media is both chemically defined and protein
17 free. And in this patent --

18 THE COURT: "Ideal," what do you contend "ideal"
19 means?

01:55 20 MS. ROYZMAN: A preferred embodiment, aspirational.

21 THE COURT: It's perfect and therefore preferred?

22 MS. ROYZMAN: Exactly, exactly. So the inventors in
23 this patent actually achieve that ideal. They disclose 61
24 known chemical compounds that don't include proteins. Proteins
25 are also chemical compounds, they're known. And they show in

1 examples 1 and 2 that that media works great. The cells grow
2 well. You make lots of antibody. And so they achieve their
3 ideal, and they're very proud of that. But in addition, they
4 recognize, just as everyone recognizes, that, you know, ideal
5 and preferred is great, but then there are lots of other
6 things. So they disclose in their embodiments here about using
7 their 61 ingredients with other things, with known supplements,
8 with chemically undefined components, such as --

9 THE COURT: Where is that in the specification?

01:57 10 MS. ROYZMAN: I will get to that in a second, Your
11 Honor. I jumped a bit with this.

12 So in addition to describing the ideal, in the summary
13 of the invention, the inventors make very clear that they're
14 not limiting themselves to the ideal and they're talking about
15 one aspect of the invention. They're just talking about a
16 composition for making a cell culture media which comprises,
17 includes the following list of 61 ingredients, among other
18 things.

19 They explain that the present invention -- and
01:57 20 Celltrion likes this statement very much -- provides chemically
21 defined --

22 THE COURT: Where is it in the patent, what column?

23 MS. ROYZMAN: It's column 4, Your Honor, lines 30 to
24 40, I believe, it's slide 9. It's the first sentence of that.

25 And the invention does provide chemically defined

1 compositions useful in the culture of eukaryotic cells because
2 they disclose 61 ingredients that are a unique combination and
3 extremely useful, and you can use them to make cell culture
4 media that either includes just those ingredients or more
5 ingredients.

6 THE COURT: You say that's the meaning of "comprise"?

7 MS. ROYZMAN: Yes.

8 THE COURT: That the chemicals, 61 chemicals listed
9 have to be in the invention, but "comprise" means that it's not
01:58 10 required that they be the only things in the compound?

11 MS. ROYZMAN: Precisely, Your Honor. And the patent
12 says this repeatedly. It says -- and here are two more quotes
13 from the patent. These are from the detailed description. One
14 is in column 5, lines 4 through 7, another from column 6.

15 THE COURT: I'm sorry. Column 5.

16 MS. ROYZMAN: Just making clear that the invention
17 provides a composition for producing a cell culture media. And
18 just like Your Honor explained a second ago, it's got to have
19 this list of 61 ingredients. And it sets forth amounts for
02:00 20 them, concentrations. And then it can have additional things,
21 wherein the media comprises. And then the other quote on slide
22 10 again is very similar. This is repeated.

23 THE COURT: I have it.

24 MS. ROYZMAN: Okay. Thank you.

25 Okay. So Your Honor asked where are these other

1 embodiments about chemically undefined components. And here is
2 an example in the detailed description. There are actually two
3 examples. This is one of them. This is column 8, Your Honor,
4 lines 4 to 21. And it states, in another embodiment of the
5 invention provides a composition comprising a cell culture
6 media, and that media is made by providing a soluble MET 1.5
7 composition, which has those 61 ingredients among potentially
8 other things. And in this embodiment, also optionally adding
9 at least --

02:01 10 THE COURT: What line is that "optionally"?

11 MS. ROYZMAN: Oh, let me see, Your Honor.

12 THE COURT: I've got it. Looks like 13.

13 MS. ROYZMAN: Yes, exactly. Thank you.

14 THE COURT: Let me see if I understand this. It says,
15 "Optionally adding at least one substance selected from the
16 group consisting of micro phenolic acid," and three other
17 things. What's the import of that language from your
18 perspective?

19 MS. ROYZMAN: Okay. So what I'd like to bring your
02:02 20 attention to is the one that I have underlined in red, which is
21 soy hydrolysate. So this is an embodiment of the invention
22 where you're optionally adding soy hydrolysate as one of the
23 additional ingredients. And soy hydrolysate, it's basically --
24 a hydrolysate is basically a digest, and this is a digest of
25 soy beans. It's a breakdown product. And as you'll see as we

1 go forward, soy hydrolysates are chemically undefined.

2 So this is an embodiment of the invention comprising a
3 cell culture media that includes adding a chemically undefined
4 ingredient. And hydrolysates, just to give some life to them,
5 they're basically nutritional supplements. It turns out that
6 they're very useful in sports medicine, bodybuilders like them,
7 cells love them, and so they're also routinely added to media,
8 and they are undefined ingredients.

9 THE COURT: "Undefined" means what?

02:03 10 MS. ROYZMAN: It means chemically undefined. It's
11 just full of -- it's a functional definition. And they just
12 think the soybeans, and it's full of unknown chemicals, so
13 unlike the list of 61 ingredients where you know you're putting
14 in this and this and that amount, for soy hydrolysates, you're
15 just basically putting in a lot of stuff. You're putting in
16 peptides of different lengths. You're putting in chemicals of
17 different varieties. And to this day -- and there's testimony
18 in the record on that, and it's undisputed, that to this day
19 hydrolysates are this undefined thing that cells like and
02:04 20 that's routinely added to media and useful for other purposes,
21 too.

22 THE COURT: Okay.

23 MS. ROYZMAN: So you also asked about where is this
24 mention of supplements. And here it is, Your Honor. It's
25 again the detailed description. And this is slide 12. And in

1 the patent it's -- the paragraph that I have here is in column
2 4, line 64, running through column 5, line 3. And what it says
3 is --

4 THE COURT: Hold on a second. Column 4, line what?

5 MS. ROYZMAN: 64, I believe, Your Honor.

6 THE COURT: I don't think so.

7 MS. ROYZMAN: It starts -- that's the first sentence.

8 Then if you go to -- I think it may be 67. "Those skilled in
9 the art." Then it goes over to the completion of that
02:05 10 paragraph on the next page.

11 And it was well understood at the time that people
12 were adding supplements of all sorts to media. And again, cell
13 culture media is something that people have been working on
14 because it's essential for biopharmaceutical production and for
15 growing cells in vitro. And the patent is making clear that
16 people are going to know what supplements to add. And that of
17 course doesn't take them out of the claim. And proteins are
18 examples of known supplements.

19 Okay. So what's Claim 1? There are two claims, Your
02:06 20 Honor, that are asserted in this patent. Claims 1 and 2.

21 Claim 2 depends on, from Claim 1. And Claim 1 is very much
22 like the various disclosure that we've been looking at. It's
23 to a soluble composition suitable for producing a final volume
24 of cell culture media, wherein the composition comprises,
25 includes the following components in the following amounts per

1 liter of the final volume of cell culture media. And then
2 there's the list of 61 ingredients in various ranges. And I
3 didn't replicate that because it's long.

4 Okay. So what are the constructions? So here is
5 Janssen's construction, Your Honor. No construction necessary,
6 or plain and ordinary meaning, nutritive media for culturing
7 cells. I'm at slide 14. Then I have Celltrion's original
8 construction, which was focused on chemically defined media as
9 well as Celltrion's alternative construction, which is more
02:07 10 focused on free of all proteins. So it picks up a lot of the
11 language of the ordinary and plain meaning, such as nutritive
12 media for culturing cells. But it puts -- it adds in the
13 limitation of free of all proteins.

14 Okay. As we discussed, just as Your Honor started the
15 discussion, there are very established claim construction
16 principles. You start with the claims and then the
17 specification. The prosecution history can be incredibly
18 important if there's a disclaimer of some kind or an argument
19 of some kind that limits the claims.

02:08 20 THE COURT: It can be, but are you relying on the
21 prosecution history?

22 MS. ROYZMAN: There's no disclaim er of any kind, and
23 Celltrion is not relying on anything here.

24 THE COURT: That's what I thought. So the intrinsic
25 evidence as a practical matter for the purpose of this *Markman*

1 issue is the claim and the specification.

2 MS. ROYZMAN: Yes. And the prosecution history, I
3 would say, confirms it because it doesn't limit it in any way.

4 THE COURT: Okay.

5 MS. ROYZMAN: Okay. And then as Your Honor stated,
6 and we agree, extrinsic evidence is way down the totem pole.

7 So let's start with the claims. And the place to
8 start is the words of the claim, so let's start there. And the
9 law makes crystal that that's just where you start. First we
02:09 10 look to the words of the claims. And here, Your Honor, we have
11 another bedrock principle of patent law, and the bedrock
12 principle is that the claims of a patent define the invention,
13 the claims have primacy.

14 So let's look at the claims. Here is Claim 1. And
15 the words of the claim are "cell culture media." Here is Claim
16 4 --

17 THE COURT: I don't need -- do I need to look at
18 anything more than Claim 1?

19 MS. ROYZMAN: I think, Your Honor, you do, because the
02:10 20 asserted and non-asserted claims inform the meaning.

21 THE COURT: Here. Let me put it differently. Do I
22 need to construe anything other than "cell culture media" in
23 Claim 1?

24 MS. ROYZMAN: No, but cell culture media should be
25 construed consistently.

1 THE COURT: That's my point. If I construe it, say,
2 your way in Claim 1, it would apply throughout the patent,
3 right?

4 MS. ROYZMAN: Exactly.

5 THE COURT: The other claims descend from Claim 1?

6 MS. ROYZMAN: Yes -- they don't all descend from Claim
7 1, but they use the same term, they use "cell culture media."

8 THE COURT: Okay. Because I've been focusing on Claim
9 1.

02:11 10 MS. ROYZMAN: I understand.

11 THE COURT: Is that okay?

12 MS. ROYZMAN: Yes, it's absolutely okay. But I think,
13 as you'll see, Claims 4 and 10 are particularly relevant
14 because they expressly claim optionally adding the soy
15 hydrolysate, so they further confirm that there is no chance
16 that the media can be chemically defined, and that's just a
17 construction that's absolutely wrong because it contradicts the
18 claims. It's something that's just truly impossible. So in
19 that context, it's relevant.

02:11 20 THE COURT: Okay.

21 MS. ROYZMAN: Okay. So what's the point of the
22 claims? They all use the term "cell culture media." None of
23 them say "chemically defined." None of them say "free of all
24 proteins."

25 "Comprising," we discussed. It means including but

1 not limited to. And that's precisely what it means here. And
2 "comprising" serves a very important function here because it
3 allows the claims to cover embodiments that are expressly
4 disclosed in the patent that include other things. So
5 "comprising" is absolutely essential.

6 What's the plain and ordinary meaning?

7 THE COURT: This is part of what I was getting at when
8 I said am I being asked to construe the term or define the
9 invention claimed in Claim 1? Because there's the term "cell
02:12 10 culture media," then it says "comprising," and it lists a
11 number of chemicals, right?

12 MS. ROYZMAN: Yeah.

13 THE COURT: So to the extent that something is
14 chemically defined, is it defined not by the term "cell culture
15 medium" but by what comes after "comprising"? Is that an
16 appropriate way to look at this?

17 MS. ROYZMAN: Well, I guess I'm not -- "cell culture
18 media" covers all types of cell culture media. And so for
19 example, if -- I'll just go back to the claim for a second. If
02:13 20 the claim "cell culture media" was construed in our view
21 contrary to all legal principles and the intrinsic evidence as
22 "chemically defined" or "free of all proteins," "comprising"
23 wouldn't help and save the day because --

24 THE COURT: Save the day for whom?

25 MS. ROYZMAN: Well, for plaintiffs. Because if "cell

1 culture media" was construed in this narrow way, then you
2 can't, through "comprising," add additional --

3 THE COURT: No. I'm probably not asking my question
4 well. I'm making the opposite point, that it appears to me
5 that the invention has to include chemicals, right?

6 MS. ROYZMAN: Oh, yeah. And they're --

7 THE COURT: Let me finish.

8 MS. ROYZMAN: Yeah.

9 THE COURT: Chemicals. But that requirement, you
02:14 10 argue -- at the moment I think it's right -- is not imposed by
11 the term "cell culture media." It's imposed by the word
12 "comprising" and the 61 chemicals that follow it. Do you agree
13 with what I just said?

14 MS. ROYZMAN: I do, Your Honor, because of course
15 those 61 ingredients are limitations of the claim.

16 THE COURT: And they're chemicals.

17 MS. ROYZMAN: They're all chemicals, 61 chemicals.

18 THE COURT: Does that make the invention chemically
19 defined?

02:15 20 MS. ROYZMAN: No, because the -- well, it depends.

21 THE COURT: The invention.

22 MS. ROYZMAN: It depends on -- you have a choice. So
23 if a media that is made that includes only these 61 ingredients
24 and no others, it's going to be chemically defined and protein
25 free. On the other hand, if it includes soy hydrolysate, it's

1 going to be chemically undefined.

2 THE COURT: So "chemically defined" means having only
3 chemicals.

4 MS. ROYZMAN: Having only known chemical compounds,
5 yes.

6 THE COURT: All right.

7 MS. ROYZMAN: So what's the plain and ordinary meaning
8 here. One, there is a heavy presumption that the language in
9 the claim carries its ordinary and customary meaning. And it's
02:16 10 also -- and this is the *Thorner* case that Your Honor referred
11 to, in which we rely on extensively, is that the patentee is
12 free to choose a broad term and expect to obtain the full scope
13 of its plain and ordinary meaning. And here, the term that was
14 selected in the claims is "cell culture media."

15 And in terms of its plain and ordinary meaning, I
16 don't believe there's any dispute among the parties what it is.
17 So here is the Oxford Dictionary that Your Honor referred to
18 earlier, and here is what it says, "Any nutritive media that's
19 designed to support the growth or maintenance of a culture."

02:17 20 In a case that we cited to Your Honor from the Federal
21 Circuit in 2013, "cell culture media" was a claim term, and the
22 Federal Circuit didn't construe it. It just set forth the
23 plain and ordinary definition. And here it is. And Your Honor
24 actually also defined a culture medium in the *Biogen* case, and
25 that's in slide 31. Your Honor said that, "A culture medium is

1 a solution that contains the nutrients required for maintenance
2 and growth of the cell," and it didn't cite anything in
3 connection with that. That's because this is its plain and
4 ordinary meaning; that's what everybody agrees it is. And
5 that's what we're relying on here.

6 It's also corroborated by the intrinsic evidence.

7 This is an exhibit that we cited in our opening brief. It's
8 intrinsic evidence. It's cited by the '083 patent. And it
9 defines -- and it's in the right timeframe, and it defines
02:18 10 "cell culture media" consistent with its plain and ordinary
11 meaning, "a nutritive solution for cultivating cells."

12 THE COURT: Where does the language in slide 32 come
13 from?

14 MS. ROYZMAN: So it comes from --

15 THE COURT: Is it in the patent?

16 MS. ROYZMAN: No. So it's in this patent. So the way
17 this works is the '083 patent cites this one. This is
18 W09808934. It's cited on the face of the '083 patent, and it
19 was part of the record for the patent. And we provided an
02:19 20 excerpt from that to Your Honor, and it's at docket number
21 149 --

22 THE COURT: That's okay. You're on slide 32 of about
23 90, so you want to decide what's important.

24 MS. ROYZMAN: Okay. The unasserted Claims 4 and 10,
25 Your Honor, are important. And that's, as I mentioned and as

1 you said, claims are construed consistently across the board.
2 And Claim 4 is to a cell culture media. And optionally adding
3 soy hydrolysate, just as we saw in the specification a second
4 ago, and this is just expressly claiming that. So this is
5 expressly claiming a chemically undefined media. Claim 10 does
6 exactly the same thing.

7 And in this case, it's undisputed, but as a
8 generality, hydrolysates are undefined. And here again in the
9 intrinsic evidence, it makes clear that a chemically defined
02:20 10 medium is distinguished from hydrolysates which contain unknown
11 components. As I was telling Your Honor, cells love them, but
12 they're just full of unknown stuff.

13 And Celltrion, in its reply brief, stated correctly,
14 "To be sure, soy hydrolysate typically" -- and we quibble with
15 "typically," but "soy hydrolysate is not chemically defined."

16 Okay. Let's turn to the specification because it's
17 important here as well.

18 THE COURT: I'm sorry. Okay. So Celltrion
19 acknowledges that?

02:21 20 MS. ROYZMAN: Yes, they do. That's at page 11 of
21 their reply brief.

22 THE COURT: Go ahead.

23 MS. ROYZMAN: Okay. So the specification is relevant.
24 And as we discussed in looking through the patent a bit, the
25 summary of the invention never says, you know, the invention is

1 a chemically defined cell culture media or anything like that.
2 It says the invention is a cell culture media. It says it
3 three times.

4 It's said throughout the patent that the invention is
5 a cell culture media. And in fact, cell culture media is
6 discussed in the patent, consistent with understanding that
7 "cell culture media" is a broader term than "chemically
8 defined" or anything like that. So there are references in
9 examples 1 and 2 to chemically defined "cell culture media,"
02:22 10 again, using both sets of terms, because "chemically defined"
11 is a subset of "cell culture media."

12 And then there are references to conventional
13 eukaryotic cell culture media. There are references, as we
14 discussed, to animal component-free cell culture media. "Cell
15 culture media" is a broad term. And it's the specification
16 most commonly, and it's all over the place, Your Honor, just
17 uses the term "cell culture media."

18 As we started discussing, "cell culture media" is not
19 limited to "chemically defined." "Chemically defined" is a
02:23 20 preferred embodiment. That's what "ideally" means.

21 THE COURT: Here. I encouraged you to speed up, but
22 now you're going a little too fast.

23 MS. ROYZMAN: Sorry.

24 THE COURT: Okay.

25 MS. ROYZMAN: Here is the definition of chemically

1 defined. It says, "Ideally, such media are chemically defined
2 such that the media compositions contain only known chemical
3 compounds." And that's preferred.

4 And the law is very clear, and here we cited *Kara Tech*
5 and *Silicon Graphics* that the patentee is entitled to the full
6 scope of his claims, and we will not limit him to his preferred
7 embodiment or import a limitation from the specification into
8 the claims.

9 And Mr. Hurst mentioned lexicography and disclaimer.
02:24 10 There's no such thing. "Cell culture media" is not redefined
11 ever in the specification. It's used broadly as the examples
12 that I illustrate it show. It is never redefined whatsoever,
13 and there is no disclaimer of any kind. No disavowal, not in
14 the specification and not in the prosecution history.

15 So here are the two statements that Celltrion relies
16 on and which they somehow describe as limiting, and it's these
17 two statements on slides 54. One, the first statement is from
18 the field of the invention, and it states, "The present
19 invention relates to chemically defined media compositions for
02:25 20 the culture of eukaryotic cells." That's just true; it does.
21 But that doesn't limit the invention to chemically defined
22 media. You can add all sorts of other things. It does
23 disclose --

24 THE COURT: Well, here. Let's pause here. This is
25 why I was asking about the distinction between the terms "cell

1 culture media" and "the invention." Here they're talking about
2 the invention, the complete thing described in Claim and Count
3 1, as I read it, not the cell culture media.

4 Is that an appropriate way to think about this?

5 MS. ROYZMAN: Well, I guess I just read the statement
6 as saying, "The present invention relates to chemically defined
7 compositions." It actually nowhere mentions "cell culture
8 media" at all. And "cell culture media" is used much more
9 broadly in the patent. You can use -- it can be chemically
02:26 10 defined or it can be chemically undefined, depending on what
11 you put in it. It just has its much broader meaning of a
12 nutritive media for culturing cells.

13 THE COURT: Is it still the case that a court can
14 change its claim construction at any time essentially up until
15 the point it instructs the jury?

16 MS. ROYZMAN: Yes, Your Honor.

17 THE COURT: Go ahead.

18 MS. ROYZMAN: Here are many other statements about the
19 invention, and these statements actually use the term "cell
02:27 20 culture media," and they make very clear, you know, one aspect
21 of the invention is a soluble composition suitable for
22 producing a cell culture media. Cell culture media is the
23 invention here. And where the reference is -- and I don't
24 think actually there are any problematic references in the
25 specification of any kind. But where the reference is to a

1 certain limitation as being the invention are not uniform where
2 other portions of the intrinsic evidence do not support
3 applying the limitation to the entire patent, it's just
4 improper to limit it. And that's *Absolute Software*. And
5 that's the law.

6 Celltrion also relies on the title, "Chemically
7 Defined Media Compositions." And again, the patent relates to
8 chemically defined media compositions. It provides 61
9 components that are useful for making cell culture media. The
02:28 10 title is not problematic in any way, but it also has no import
11 on claim construction. Even if it did, the bar on importing
12 limitations from the written description into the claims
13 applies no less forcefully to a title. And the Federal Circuit
14 has made clear that if they're not going to read in limitations
15 from the specification, they're certainly not going to read
16 limitations into the claims from the patent title. And Your
17 Honor pointed out the same principle. In the *Biogen* case, you
18 stated, "The Federal Circuit has noted the near relevancy of
19 the patent title to claim construction."

02:29 20 And also, as we discussed and as dispositive here,
21 there are chemically undefined embodiments in the
22 specification, and they're described as embodiments of the
23 invention, optionally adding the soy hydrolysate. And there
24 are two such embodiments. There's the one we discussed, which
25 comes after this, that's MET 1.5 media. Then there's this one

1 in column 7, line 53 through column 8, line 3. And then at the
2 very end of this paragraph, it states, "In this embodiment of
3 the invention, the media composition that is the product of
4 this process" --

5 THE COURT: Where are you reading in the patent?

6 MS. ROYZMAN: Let's see. Your Honor, this paragraph
7 begins on column 7, line 53 in one embodiment of the invention.
8 And soy hydrolysate is mentioned in column 7, line 63. And
9 then a name is given to this embodiment, and that starts at
02:31 10 line 67. "In this embodiment of the invention, the media
11 composition has been named MET media."

12 THE COURT: What's the import of it being named MET
13 media?

14 MS. ROYZMAN: I think at various places in its brief
15 Celltrion tried to imply that MET media is just limited to the
16 61 ingredients and doesn't include other things and is
17 necessarily chemically defined, and this is defining an
18 embodiment of the invention that's necessarily chemically
19 undefined because it includes soy hydrolysate as MET media.

02:32 20 THE COURT: That's the invention. This isn't talking
21 about cell culture media.

22 MS. ROYZMAN: It is, Your Honor. If you look at the
23 top.

24 THE COURT: I see, "In one embodiment, the invention
25 provides a composition comprising a cell culture media made

1 from the steps comprising" --

2 MS. ROYZMAN: Then it says, "providing a soluble MET
3 composition." And that's described earlier. And that soluble
4 MET composition includes 61 ingredients, plus potentially
5 others. And then it says you do certain things, and you can
6 also optionally add at least one substance selected from this
7 group, including soy hydrolysate. And then it says, "In this
8 embodiment of the invention, the media composition is referred
9 to as 'MET media.'"

02:33 10 THE COURT: Okay.

11 MS. ROYZMAN: But it's an embodiment of the invention
12 that directly relates to cell culture media.

13 Your Honor, I'm just going to move along, but it's
14 exactly the same thing with MET 1.5 media in that paragraph, in
15 column 8, this is another chemically undefined embodiment in
16 the specification.

17 And this is -- I don't believe we cited this case in
18 our brief, but it stands for the very important principle where
19 claims are interpreted to include a specific embodiment. It's
02:33 20 incorrect to construe the claims to exclude that embodiment.
21 That just makes sense. And here, chemically undefined
22 embodiments are being claimed in Claims 4 and 10, and they're
23 being specifically expressly disclosed in the specification in
24 column 7 and 8.

25 Okay. So now we turn from the "chemically defined"

1 discussion to "not limited to protein free." Celltrion's -- so
2 here is Celltrion's original construction. I have it on top.
3 I have all the constructions. And they basically defined
4 "chemically defined media," which is, as the construction for
5 cell culture media, that's not its ordinary and plain meaning
6 and is incorrect for that reason. It contradicts the
7 specification. It contradicts the claims. But in addition --

8 THE COURT: Actually -- all right. Now you're on 65
9 of 89?

02:35 10 MS. ROYZMAN: Yes.

11 THE COURT: I want to take a very brief break, not
12 more than five minutes right here, and then you'll finish. And
13 I'll take another break, and we'll go to the defendant. Okay?
14 Court is in recess.

15 (Recess taken 2:35 p.m. to 2:41 p.m.)

16 THE COURT: Ms. Royzman, you may proceed.

17 MS. ROYZMAN: Thank you, Your Honor. So going back to
18 slide 65, Celltrion's original construction and what they
19 described still as their primary construction, which is
02:41 20 completely inconsistent with their alternative construction,
21 was focused on "chemically defined media" and tried to shoehorn
22 "free of all proteins" into that, and that was based on the
23 misreading of that "ideally" sentence, which I'll get to in a
24 second, because as a matter of science and as a matter of
25 reading that sentence, this doesn't make any sense. Proteins

1 are chemically defined. You know they're amino acids. You
2 know they're a structure, they're known chemical compounds. So
3 this definition of "chemically defined media" is not supported
4 by the specification and just really also doesn't make sense
5 for this additional reason.

6 Here is an example from the intrinsic evidence, and
7 again it's cited in the '083 patent, and we had provided an
8 excerpt of this to Your Honor, though we didn't provide this
9 particular page, and I can. But it makes very clear that
02:43 10 defined media contain no undefined supplements, such as
11 hydrolysates, and instead incorporate defined qualities of
12 known things such as proteins.

13 In our brief we had cited the molecular biology of the
14 cell, which makes the same point that the basically defined
15 media contain one or more specific proteins because proteins
16 are just defined. You know, they're amino acids, and you know
17 exactly what you're putting in. So that didn't make any sense.
18 In addition, "protein free" is a preferred embodiment.

19 THE COURT: Is it even -- sorry. "Protein free,"
02:44 20 you're looking at the "ideally" language in the background of
21 invention?

22 MS. ROYZMAN: Yeah.

23 THE COURT: Does the background of invention describe
24 embodiments?

25 MS. ROYZMAN: It doesn't -- it sets forth an ideal,

1 but those 61 --

2 THE COURT: No. That's not -- I know you're very
3 close to this. But look, this the background of invention
4 doesn't -- is this where you find embodiments in the background
5 of invention section of a patent?

6 MS. ROYZMAN: No. You find them later.

7 THE COURT: Right. Okay. But this is not -- it
8 seemed to me that this statement is not even specific to the
9 invention claimed in Claim 1 or in the patent. It's talking
02:45 10 about, you know, sort of the general universe of things.

11 MS. ROYZMAN: That's exactly right, Your Honor.

12 THE COURT: I thought you might say that eventually.
13 Go ahead.

14 MS. ROYZMAN: I needed your help. But the 61
15 ingredients -- okay. In any case, the construction that the
16 defendants were advocating of "chemically defined" was based on
17 a misreading of this sentence in the background.

18 And listen, why do they pay attention to this -- so
19 much attention to this one sentence, right? I think that's an
02:45 20 interesting question. And that's because this is the only
21 sentence in the patent, anywhere in the patent, that mentions
22 "free of all proteins." It's the only one. And why are they
23 interested in that? Because that's the basis of their
24 noninfringement position. So they would like to read in,
25 through claim construction, one way or another, put in "free of

1 all proteins" because then they can say, Oh, I don't have cell
2 culture media; I'm done. That's what this dispute is about.
3 And cell culture media is just not -- in this patent is not
4 free of all proteins.

5 THE COURT: It's not free of all proteins. And I
6 think it's your argument -- or is it your argument that the
7 invention doesn't require free of all proteins because there's
8 comprising language in Claim 1?

9 MS. ROYZMAN: Absolutely. And it describes the
02:46 10 addition of supplements. That was all well known and made a
11 lot of sense.

12 THE COURT: Okay. Go ahead.

13 MS. ROYZMAN: Okay. So again, any particular
14 embodiments are not limiting. We've already gone through this
15 law. This is more of the same.

16 And the specification, as we discussed --

17 THE COURT: But -- okay. Go ahead. Go ahead.

18 MS. ROYZMAN: So we looked at this passage, Your
19 Honor. It's talking about the addition --

02:47 20 THE COURT: Which passage?

21 MS. ROYZMAN: It's the one in column 4 at the very
22 bottom of column 4, and it goes on to line 5 through -- column
23 5, line 3. It talks about, basically those skilled in the art,
24 they're going to know the supplements to add to make this
25 culture successful.

1 THE COURT: And you say supplements can be something
2 other than the 61 chemicals?

3 MS. ROYZMAN: Absolutely, and they can be proteins.

4 THE COURT: And could be proteins.

5 MS. ROYZMAN: And I took the deposition of Celltrion's
6 expert, and I asked him that question. I said at the time in
7 2004, were persons of ordinary skill in the art supplementing
8 cell culture media with proteins for successful culture, and he
9 agreed, and he gave an example.

02:48 10 And those other things that we looked at both from the
11 intrinsic evidence and the textbook also talked about
12 supplementing media with proteins. This is just something that
13 people were doing and that people do to this day.

14 Okay. As Your Honor said, we look through the
15 prosecution history. Celltrion looked through the prosecution
16 history. Prosecution history is often very important in claim
17 construction. Here it confirms that "cell culture media,"
18 "cell culture media." Those terms were never amended. They
19 weren't changed in any way so there's nothing here, no
02:49 20 limitation of any kind on cell culture media based on the
21 prosecution history. The prosecution history doesn't limit the
22 meaning of "cell culture media" in any way and is not at issue
23 here.

24 THE COURT: Okay.

25 MS. ROYZMAN: Okay. Extrinsic evidence. So as Your

1 Honor said, it's at the bottom, and it can't contradict. And
2 opinion testimony on claim construction has to be treated with
3 utmost caution, and you only look at it in instances where you
4 otherwise can't construe, and such instances will rarely, if
5 ever, occur. And why is this important?

6 And Your Honor at the very beginning cited exactly
7 this language. It is because testimony generated at the time
8 of litigation for the purpose of arguing noninfringement or
9 invalidity suffers from bias that's not present in the public
02:50 10 record.

11 So here is Celltrion's expert. It's Dr. Panayotatos.
12 This is -- as he describes himself and we had cited this in our
13 answering brief. He basically hasn't done science for the last
14 20 years. He's been a patent litigation consultant. He
15 describes himself as a nontestifying technical expert, hands-on
16 experience.

17 THE COURT: Nontestifying?

18 MS. ROYZMAN: What?

19 THE COURT: Nontestifying?

02:50 20 MS. ROYZMAN: Nontestifying technical expert. Also
21 describes himself --

22 THE COURT: So if I thought this was sufficiently
23 important, which I don't, and wanted to hear his testimony
24 subject to cross-examination, he wouldn't -- that's not what he
25 does?

1 MS. ROYZMAN: Your Honor, he does both. I'm just
2 listing how he describes himself.

3 THE COURT: All right. It doesn't matter. That's a
4 digression. Go ahead.

5 MS. ROYZMAN: Okay. So in any case, he provides claim
6 construction assistance, as he did here.

7 THE COURT: How much does he get paid an hour?

8 MS. ROYZMAN: I don't recall, Your Honor. It's in the
9 deposition transcript.

02:51 10 THE COURT: If we ever try this case, the jury will be
11 very interested in that question, if he gets to testify.

12 MS. ROYZMAN: Yes.

13 THE COURT: Anyway, he wouldn't get to testify on the
14 claim meaning, if he ever got to testify on anything. That's
15 the main thing jurors pay attention to. Anyway.

16 MS. ROYZMAN: Yeah. Well, his primary source of
17 income for the last 20 years has been litigation consulting.
18 We filed, as I mentioned, as part of our answering brief in
19 response to the declaration from Dr. Florian Wurm, who was a
02:52 20 full professor and is now honorary professor meritus at the
21 Swiss Federal Institute.

22 THE COURT: It's fine. It's fine.

23 MS. ROYZMAN: As I said, we don't really think this
24 should play any role.

25 THE COURT: Okay.

1 MS. ROYZMAN: And I took the deposition of Celltrion's
2 expert, and here is what he had to say ultimately. He agreed
3 with Janssen on ordinary meaning of cell culture media because
4 that's just indisputable, just as Your Honor stated it in your
5 Biogen decision. He agreed that hydrolysates are chemically
6 undefined. Are all the chemical compounds in the soy
7 hydrolysate defined? No. In fact, he said, because it's true
8 to this day, I think it's impossible to characterize all of the
9 agreed ingredients in soy hydrolysate. This just makes the
02:53 10 chemically defined media construction impossible. He agreed,
11 as we saw, that proteins are known supplements.

12 And Celltrion, the day prior to his deposition, and as
13 I said, after our opening brief, supplied us with their
14 alternative construction, "nutritive media free of all proteins
15 for culturing eukaryotic cells," and so I put that construction
16 in front of him and asked him what he thought of it. And he
17 said it was incorrect, and he marked up the construction
18 accordingly. So Celltrion's expert agrees with us that the
19 alternative construction is wrong. That exhibit is cited in
02:54 20 our brief, and it's provided to Your Honor, and it's here on
21 slide 88.

22 THE COURT: Okay.

23 MS. ROYZMAN: But that's the end of my presentation,
24 Your Honor. I think this is a uniquely simple claim
25 construction.

1 THE COURT: Wait a minute. 88, you say is the
2 defendants' expert saying that the defendants' alternative
3 construction is wrong?

4 MS. ROYZMAN: Well, there's testimony on that, but in
5 addition, I gave him the -- I gave him the piece of paper. I
6 gave him an exhibit with the primary construction and the
7 alternative construction. And after he testified that the
8 alternative construction is incorrect, I asked him to reflect
9 it on the exhibit. And he did. He wrote that it's wrong, and
02:55 10 he signed it on May 13, the day after that construction was
11 provided to us, and that's before Your Honor.

12 THE COURT: That was fun, wasn't it?

13 (Laughter)

14 MS. ROYZMAN: It really was. I was surprised that I
15 enjoyed it.

16 THE COURT: You get to take a deposition. All right.

17 MS. ROYZMAN: That's it, Your Honor.

18 THE COURT: All right. We'll take a ten-minute break
19 and resume at 3:05. Court is in recess.

03:14 20 (Recess taken 2:55 p.m. to 3:05 p.m.)

21 THE COURT: Mr. Hurst, do you have some more slides
22 for me, too?

23 MR. HURST: I do, Your Honor.

24 THE COURT: This booklet will be Exhibit F. Go ahead.

25 MR. HURST: Your Honor, I guess I want to start out in

1 an area of agreement. There is no question -- and I agree --
2 that normally, the ordinary meaning of a term should control,
3 unless it's been disavowed or the patentee acted as a
4 lexicographer. And I do think both of those things occurred
5 here. Let me explain why as I walk through my presentation.

6 One key thing here is, the ordinary meaning of a term,
7 it obviously has to be considered in the context of all the
8 intrinsic evidence, and particularly the specification which
9 *Phillips* describes as the single most important piece of
03:15 10 evidence for construing claims, the specification itself. One
11 of the things that I think that Janssen is doing that the
12 Federal Circuit says you shouldn't be doing -- and this is from
13 the *Retractable* case --

14 THE COURT: Which --

15 MR. HURST: Sorry. Slide 3. You asked a question
16 earlier. You said, Am I supposed to construe the actual
17 invention or the term itself. I said, You're construing the
18 term, but you have to consider the scope of the actual
19 invention. And that's what the Federal Circuit teaches, for
03:16 20 instance, in *Retractable*. When construing claims, we strive to
21 capture the scope of the actual invention rather than strictly
22 limit the scope of claims to disclosed embodiments or -- and
23 this is what I really think that Janssen is doing here -- or
24 allow the claim language to become divorced from what the
25 specification conveys is the invention. The core dispute here

1 is whether the claimed cell culture media must be chemically
2 defined.

3 THE COURT: The claim is not "cell culture media. The
4 term is cell culture media, but that's only part of the
5 definition of the claim.

6 MR. HURST: The claim describes a cell culture media
7 for sure, and the question is whether that cell culture media
8 has to be chemically defined. Just to be clear on something --
9 I think counsel was clear, but I want to make sure we're all on
03:17 10 the same page. Even if you have 61 chemically defined
11 ingredients, if you add one ingredient that's not chemically
12 defined, you can no longer describe that cell culture media as
13 a chemically defined cell culture media. So adding one --

14 THE COURT: Right. So is soy hydrolysate chemically
15 defined?

16 MR. HURST: Typically, it can be.

17 THE COURT: Is it necessarily chemically defined?

18 MR. HURST: No.

19 THE COURT: All right. So they point to an embodiment
03:17 20 that includes "soy hydrolysate," if I'm pronouncing it right.

21 MR. HURST: I'll get to this.

22 THE COURT: Why don't you tell me now.

23 MR. HURST: No. I'm going to answer your question.

24 Yeah. So they cite an article in their patent specification
25 among the list of art, and that article talks about soy

1 hydrolysates, and it talks about effort to make them defined.

2 So Claim 4 says, Optionally, you can add all
3 chemically defined things, and they include in the list "soy
4 hydrolysate." When you're writing a claim, Your Honor, you're
5 writing for the future. You're saying, you know, I want to
6 make sure that I capture my intention. And they're literally
7 citing an article talking about efforts and progress towards
8 making the components of a soy hydrolysate.

9 THE COURT: But it's not -- and I think you just told
03:18 10 me and I think they pointed out your expert said -- what's the
11 soy called, "soy" what?

12 MR. HURST: "Hydrolysate," "hydrolysate."

13 THE COURT: "Soy hydrolysate." I think you just told
14 me it's not always chemically defined.

15 MR. HURST: It's true it's not always chemically
16 defined.

17 THE COURT: So would a person ordinarily skilled in
18 the art in 2004 or now know that?

19 MR. HURST: What they would know if they read the
03:19 20 article that's cited right on the patent is that there were
21 efforts being made to try to turn it into something that is
22 chemically defined.

23 THE COURT: So there's an effort being made to try to
24 turn it into something chemically defined, but at that time it
25 wasn't chemically defined. I mean, people have been making

1 efforts forever to turn iron into gold or something.

2 MR. HURST: Yeah. But think of it this way. All that
3 means, though, if we're right about the claim construction,
4 chemically defined, which I think we are, I'm going to show you
5 pieces of the case law.

6 THE COURT: Go ahead.

7 MR. HURST: But if we were right -- just to make sure
8 I finish my thought -- if the soy hydrolysate is -- if we're
9 right, if you add soy hydrolysate and it's not chemically
03:20 10 defined, it would fall outside the scope of the claims. If you
11 and add soy hydrolysate and it is chemically defined, it would
12 fall within the claims.

13 THE COURT: No. All right. I'm construing "cell
14 culture media." I'm not construing right now the invention.
15 And I mean, I think -- I didn't spell this out, but just so you
16 can keep it in mind, and then you go ahead. It seems to me
17 that "cell culture media" had a plain and ordinary meaning.
18 I'm reminded, without any controversy, I used it in *Biogen* in
19 2000. And then there's the comprising language that tells you
03:20 20 you need certain chemically defined ingredients in certain
21 proportions. But in my view, "comprising" means you have to
22 have these things in these proportions, but the compound
23 doesn't have to be limited to those things.

24 MR. HURST: I'm afraid to get deep into everything all
25 at once, but a couple of problems with that. One is if you

1 construe "comprising" to allow chemically undefined elements,
2 you're literally saying that the claimed invention can cover
3 things the specs never put in there.

4 THE COURT: You can get to that, but that's not the
5 way I read the spec so far. Go, do your way.

6 MR. HURST: Okay. The core issue here is whether the
7 cell culture media that's claimed in Claim 1 has to be
8 chemically defined. That's the core issue. Your Honor, I'm
9 going to walk through, from top to bottom, this patent. Title
03:21 10 abstract, description of the present invention, need in the
11 art, examples, claims, every single one supports, in our view,
12 the limited scope of the cell culture media that's being
13 claimed, which is that it's chemically defined and not
14 chemically undefined.

15 If we're right that cell culture media is chemically
16 defined, then it follows from the definition -- this is where
17 they became a lexicographer -- they defined "chemically
18 defined." They have a definition of it, and it includes "free
19 of all proteins." So the core, the main issue, does the term,
03:22 20 does the term that's claimed in Claim 1, does it have to be
21 chemically defined?

22 THE COURT: If they wanted it to be chemically
23 defined, why didn't they say "a chemically defined cell culture
24 media"? Because it's unmodified --

25 MR. HURST: It's a fair point.

1 THE COURT: *Thorner* talks about unmodified.

2 MR. HURST: It's a fair point, except if that was the
3 way you resolved claim construction issues, they would never,
4 no claim term would ever take on a meaning other than its
5 ordinary meaning.

6 THE COURT: But that is one thing I'm supposed to look
7 at, isn't it? Didn't *Thorner* tell me to look to see whether
8 it's modified?

9 MR. HURST: You look at the ordinary meaning. I'm
03:23 10 hearing you.

11 THE COURT: I don't know if we're -- I think that's
12 what the -- anyway. Here. Let me check. Why don't you go
13 ahead.

14 MR. HURST: Sure. Before I start walking through the
15 patent, though, I just wanted to make one sort of global point,
16 which we think is a core problem with Janssen's proposed claim
17 construction, Your Honor. This is from the *SciMed* case from
18 2001.

19 THE COURT: What slide are you on?

03:24 20 MR. HURST: I'm on slide 8. *SciMed* is probably one of
21 the most widely --

22 THE COURT: 8?

23 MR. HURST: Slide 8, yes. It says *SciMed*. Are you
24 using their slides?

25 THE COURT: Right. So *SciMed*?

1 MR. HURST: *SciMed*.

2 THE COURT: I see it.

3 MR. HURST: Here is one of the core problems we see
4 with Janssen's construction. *SciMed* is one of the most widely
5 cited Federal Circuit cases on claim construction, probably
6 outside of *Phillips* itself. It's certainly in the top handful.
7 But what it says, it teaches, is where the specification makes
8 clear that the invention does not include a particular feature,
9 that feature is deemed to be outside the reach of the claims of
03:25 10 the patent, even though the language of the claims read without
11 reference to the specification might be considered broad enough
12 to encompass the feature in question. Okay? That's the rule.

13 Their specification, Your Honor, in vigorous terms is
14 explaining the problem they're trying to solve. They're trying
15 to solve the problem of having adventitious particles. These
16 are particles that just find their way in -- they're not
17 intended. They're undefined. They can be bacterial. They can
18 be virus. They can be prion particles. Prion particles have
19 proton material that can cause problems. They're telling you
03:26 20 keep these things out. That's what they're saying. They're
21 animal-derived components, protein growth factors, which can
22 slide in with bovine serum, they're saying all these things
23 keep them out.

24 THE COURT: I assume you're going to take me through
25 it column by column.

1 MR. HURST: I will. I just wanted to make my global
2 point here. So all these things they say keep out, if you
3 construe the claims the way they're suggesting, they all can be
4 included in the claims, and that's what *SciMed* teaches you you
5 should not do.

6 THE COURT: But then you have to persuade me that all
7 these things say, "Keep it out."

8 MR. HURST: And I will, I'm going to do my best at
9 least. And there's other cases like *Lizard Tech* from 2005.

03:26 10 THE COURT: That's okay. There's also principle that
11 you don't import limitations from the specification into the
12 claims unless, essentially, the specification communicates that
13 it's required.

14 MR. HURST: Yeah. Well, I would say it differently.
15 I would say, unless the specification says this is one of our
16 goals, to overcome this shortcoming, that's my invention.
17 You're disavowing the shortcoming as being part of your
18 invention.

19 THE COURT: They didn't say that in the prosecution
03:27 20 history, did they?

21 MR. HURST: The prosecution history doesn't help
22 either side. If there was a piece of prosecution history that
23 helped Janssen, you would have heard about it. It doesn't help
24 either side.

25 Okay. So let's walk through it. The title and the

1 abstract, Your Honor, title and the abstract, I wouldn't say
2 the title itself is anything other than a chip on my side.
3 When they decided, Hey, what's the title of my patent? They
4 said, "Chemically defined media compositions."

5 THE COURT: No, but that's -- again, that may be -- I
6 don't know. Maybe I'm not thinking about this right. Even if
7 that were the invention, it doesn't, to me, mean that cell
8 culture media includes the term "chemically defined." Because
9 even if the invention had to be chemically defined, if all of
03:28 10 that were in the term "cell culture media," some of the
11 language, additional language in the claim might be
12 superfluous. Anyway. But go ahead, keep going.

13 MR. HURST: I think I know what you're getting at.
14 Let me pick a spot to hopefully elaborate on that point.

15 Just really quickly, the Federal Circuit does look at
16 the title of the invention to help. In this case, for
17 instance, the *Nintendo* case we cite here, 2016 from the Federal
18 Circuit. The question was whether "handheld device," should it
19 be any handheld device, or should it be limited to a "handheld
03:29 20 direct-pointing device." And the title said, "Easily
21 deployable interactive direct-pointing system." That was one
22 of the things. So they limited the broader scope of the
23 ordinary meaning. Same with the abstract. Federal Circuit
24 2000. "We have frequently looked to the abstract to determine
25 the scope of the invention," and they cite a series of cases.

1 What does their abstract say? The title says, "Chemically
2 defined media compositions."

3 THE COURT: What number is that one, please?

4 MR. HURST: Slide 16.

5 THE COURT: Okay.

6 MR. HURST: So I think this is where -- just because I
7 wanted something in front of me. See where the abstract says,
8 "Chemically defined media compositions for the culture of
9 eukaryotic cells are disclosed." The abstracts here, you're
03:30 10 telling people, "Here is my invention."

11 So just to be clear, under Janssen's construction,
12 they're saying all of their claims cover both chemically
13 defined media compositions and chemically undefined media
14 compositions. They're saying they cover both. And yet the
15 title and the abstract both point to only, only, chemically
16 defined media compositions. So that's the title in the
17 abstract.

18 So if you keep going along, I want to focus first on
19 present invention. Your Honor, "present invention," it's a
03:30 20 meaning that carries a lot of weight in claim construction.

21 THE COURT: "Present invention" is where?

22 MR. HURST: It's where in the patent?

23 THE COURT: Right.

24 MR. HURST: I was going to go through the case law
25 first, but let's go through the patent. If you look at "Field

1 of Invention," it's in column 1.

2 THE COURT: "Field of Invention."

3 MR. HURST: "The present invention relates to
4 chemically defined media compositions." They don't say, "Our
5 present invention also includes chemically undefined media
6 compositions." They only say "chemically defined media
7 compositions." It's in other places as well. Remember, their
8 claim construction is trying to include chemically undefined
9 media compositions. For whatever reason -- not for whatever.
03:31 10 I think the reason is because they think that's what their
11 invention is, only chemically defined.

12 THE COURT: Then why would they use the word
13 "comprising" instead of -- I mean, what you're arguing would be
14 pretty easy to say clearly.

15 MR. HURST: That is always true in any claim
16 construction hearing, Your Honor. It's always, always, always
17 true, whatever shortcoming --

18 THE COURT: No, but what does "comprising" mean?

19 MR. HURST: "Comprising" means you can add
03:32 20 additionally chemically defined ingredients. That's what it
means. Take a look at column 4 -- I'm going to give you
21 another example of present invention. And it's line --
22

23 THE COURT: No, no. Okay.

24 MR. HURST: Line 30.

25 THE COURT: Okay. "Field of Invention. The present

1 invention relates to chemically defined immediate media
2 compositions for the culture of eukaryotic cells." Remind me
3 what "eukaryotic" means.

4 MR. HURST: It's a particular kind of cell. There's
5 eukaryotic and -- I know what the answer is.

6 THE COURT: It's not material to this.

7 MR. HURST: Prokaryotic.

8 THE COURT: Okay. Go ahead.

9 MR. HURST: If you go to column 4, you'll see another
03:32 10 present invention. Line 30, "The present invention provides
11 chemically defined compositions useful in the culture of
12 eukaryotic cells."

13 This comes up a lot in claim construction. If you
14 take a look at slide 19, Your Honor, "We have found disavowed
15 or disclaimer based on clear and unmistakable questions by the
16 patentee that limit the claims such as 'the present invention
17 includes' or 'the present invention is,' or 'all embodiments of
18 the present invention are.'" Here we have language that's
19 equivalent to "the present invention is." "The present
03:33 20 invention provides chemically defined compositions useful in
21 the culture of eukaryotic cells." So to construe the claims to
22 include "chemically undefined compositions" would be contrary
23 to, we believe, to this case law.

24 THE COURT: Let me see *Luminara*.

25 Okay. I've read *Luminara*. It reiterates and perhaps

1 amplifies Thorner.

2 MR. HURST: Also, we have a string cite of cases that
3 rely on presentation invention language to help construe
4 claims. It's page 6 of our reply brief, our last brief.

5 THE COURT: Okay.

6 MR. HURST: It's footnote 2, there's a long string
7 cite. Fairly famous one is *Verizon Services*, which I have on
8 slide 18, "When a patent describes the features of the present
9 invention as a whole, this description limits the scope of the
03:36 10 invention." Lots of cases say essentially that.

11 THE COURT: What's the slide you have up?

12 MR. HURST: Sorry. Slide 18 has *Verizon* as another
13 example. And in our brief we had many more examples of that
14 same concept.

15 THE COURT: Go ahead.

16 MR. HURST: It's not just that they say it's their
17 present invention in those words, Your Honor. It's when they
18 describe what they came up with to solve the problems in the
19 priority art. It's called "need in the prior art" at this
03:37 20 point. Slide 21. I go through it a step at a time. Maybe it
21 would be easier just to go through the patent itself. But the
22 point here is, when you read through this patent, they're
23 literally saying, you know what the art needs? Chemically
24 defined cell culture media. That's what the art needs. And
25 they move over to the invention and they describe chemically

1 defined cell culture media in two examples.

2 If I can walk through the patent --

3 THE COURT: That would be good.

4 MR. HURST: Let's go to column 1, lines 32 through 38.

5 THE COURT: This is in the background of the
6 invention?

7 MR. HURST: It is. And this is important. What it's
8 showing here is this is the shortcoming that existed in the
9 prior art. Here is why my invention solved that problem and
03:38 10 why they call it their present invention.

11 We went through this. I think you went through this
12 in the earlier presentation. "Adventitious particle
13 contamination of conventional eukaryotic cell culture media can
14 result from the incorporation of animal-derived components and
15 protein growth factors into conventional media." And
16 conventional media had a lot of undefined components.

17 It has a couple key problems, Your Honor. One is
18 totally inconsistent. When you're randomly putting things in
19 your cell culture media, you don't know from batch to batch
03:39 20 whether it's going to be a good media for growing cells. But
21 secondly, it can cause infections. That's what they say here.
22 "Such contaminations can occur when animal-derived components
23 are harvested from an animal harboring disease, causing
24 bacteria, viruses or prions." A prion is a material that can
25 cause problems and it's unpredictable.

1 If you go to column 1 at 17 through 24, they say when
2 you add these undefined chemical compounds, pieces of proteins,
3 if it's undefined, it can cause a serious potential problem.

4 They talk about the fact, you'll see the sentence that
5 begins, "Such contaminants." "Such contaminants in a
6 biopharmaceutical are capable of causing patient infections and
7 disease and may limit yields due to increased metabolic burdens
8 on the host production cell line." These are what I talked
9 about before. Two problems, unpredictability and how good your
03:40 10 cell culture media is going to be. When you're putting things
11 that are undefined into the body, it can cause problems.

12 They talk about -- if you look at lines 25 through 43,
13 they talk about the fact that for instance, unbeknownst to the
14 company making the cell culture media, the animal could have a
15 disease that's not apparent, like mad cow disease, and that's
16 happened. The disease from the animal, even through normal
17 processing, doesn't end up working its way into the human
18 being. That's what happened with mad cow disease. So that's a
19 risk that people knew about. They talk about it here. So when
03:40 20 you're putting undefined things in your cell culture media,
21 there can be problems.

22 Now if you take a look at slide -- I'm sorry. If you
23 look at lines 50 through 67, this is where they start talking
24 about what they're going to do about it.

25 THE COURT: Did you skip 46 deliberately, the

1 "ideally"?

2 MR. HURST: No, no. I want to get to that, too. We
3 like that. We can do it now.

4 So they say, "Adventitious particle contamination can
5 be avoided by culturing eukaryotic cells in animal component
6 free cell culture media." Then they say, "Ideally, such media
7 are 'chemically defined,'" they then define that phrase. "Such
8 that the media composition contains only known chemical
9 compounds and are free of all proteins, even those not of
03:41 10 animal origin such as recombinant proteins." So that you see
11 where they define that.

12 THE COURT: Well, a couple of things. One, this is in
13 the background of the invention, so it doesn't directly address
14 what the invention is correct.

15 MR. HURST: Can I push back on that a little bit?
16 It's in the background. I agree with that. But they define
17 the term "chemically defined," which they use in the
18 description of their present invention. So that definition
19 gets taken up into the field of the invention.

03:42 20 THE COURT: But here it says, "Ideally," and "ideally"
21 to me -- and I mean, I think it has a conventional meaning. It
22 means preferably; it would be perfect if you can achieve this.
23 It doesn't itself in isolation say necessarily, and also, as I
24 said, it's not directly speaking of the claimed invention.
25 It's sort of the goal.

1 MR. HURST: It is absolutely true. They're saying in
2 the background, they're saying all these problems could be
3 avoided ideally, right, if you use -- and they define it -- if
4 you use a chemically defined cell culture media. But then take
5 it to the logical conclusion, Your Honor. Then they say, By
6 the way what's any present invention?" The present invention
7 relates to a chemically defined media cell culture." So
8 they're saying they have now accomplished what in their
9 background they're saying is the goal. The goal, what's ideal.
03:43 10 Chemically defined is what's ideal. They say it in the
11 presentation invention, they say it in the title and abstract.
12 That definition carries over beyond the background, is my
13 point.

14 THE COURT: Okay.

15 MR. HURST: So then, the very last paragraph before
16 they get to describing the invention, summary of the invention,
17 right after they say, Hey what's the ideal? What's the goal?
18 What are we hoping to achieve here in the world to obviate all
19 these problems with the prior art? Chemically defined. What's
03:44 20 the first line say? "Chemically defined media compositions
21 optimal for production of" --

22 THE COURT: Sorry. I don't know where you're reading.

23 MR. HURST: Sorry, Your Honor. Second to last
24 paragraph, starting line 50, column 1.

25 THE COURT: Go ahead.

1 MR. HURST: So again, now they say, Here is the ideal.
2 Chemically defined media compositions. Then they say, Okay, if
3 you wanted to do that, if you wanted to do a chemically defined
4 media composition, what would you have to accomplish? And they
5 say, "Chemically defined media compositions optimal for
6 production of biopharmaceuticals, such as antibodies, must
7 satisfy several different criteria." Then they go through the
8 criteria. So they say, Here is the goal, chemically defined.
9 Here is what you need to meet that goal. And look at the last
03:45 10 sentence of that column, "Thus, a need exists" -- not for
11 chemically undefined, but -- "a need exists for chemically
12 defined media compositions."
13 THE COURT: What slide are you looking at?
14 MR. HURST: Slide 27. So they're setting up the
15 problem that they solved as chemically defined, a good
16 chemically defined media composition. "The need exists for a
17 chemically defined." Not "chemically undefined." "Chemically
18 defined."

19 Okay. Then you'll see right in the next column, it
03:46 20 says "Summary of the Invention," right? They end up giving two
21 examples.

22 THE COURT: Where?

23 MR. HURST: Examples 1 and 2. Let me get to them.

24 You know, my cites here just say examples 1 and 2. So if you
25 page through, you'll see -- columns 9 and 10.

1 THE COURT: Column 9?

2 MR. HURST: And 10, yeah.

3 THE COURT: Before you get to column 9, please --

4 MR. HURST: Sure.

5 THE COURT: -- I thought you were going to show me
6 column 4, line 30.

7 MR. HURST: Yeah. I thought I should do that.

8 THE COURT: That says, "The present invention provides
9 chemically defined compositions useful in the culture of
03:47 10 eukaryotic cells." Does that have any significance?

11 MR. HURST: It does. It's another -- I gave you two
12 examples. There's only two here. One is the field of
13 invention, and one is line 30. They both say the same thing.
14 Chemically defined is what they're telling you is their present
15 invention.

16 THE COURT: Then you just heard Janssen argue that at
17 the end of column 4, line 67, going over to the next page,
18 "Those skilled in the art will recognize other myeloma cell
19 lines and myeloma-derived cell lines as well as any supplements
03:48 20 required for the successful culture of such cells."

21 Are myeloma -- is this saying that -- well, the
22 plaintiff says this would tell one ordinarily skilled in the
23 art that in addition to the 61 chemicals that comprise the
24 invention, there can be other supplements.

25 Are myeloma cell lines chemically defined? It's in

1 column 5, line 1.

2 MR. HURST: I think the cell line is what you use to
3 create the culture itself. That's not something you put into
4 the cell culture media. But the supplements, though, the
5 supplements, it doesn't shade anything on the question, right,
6 because the supplements can be either defined chemicals or
7 undefined chemicals.

8 THE COURT: But here it doesn't say, "any chemically
9 defined supplement." It says, "Any supplement required for the
03:49 10 successful culture of such cells."

11 MR. HURST: True. And if I'm right, how the
12 presentation invention is described, and how the problem is
13 described and how the need is described, title, abstract, that
14 would just mean you ought to be using supplements that are
15 chemically defined to carry out the claimed invention.

16 THE COURT: Okay. That, I think somewhat turns the
17 inquiry on its head. Now, where is the reference to soy that
18 was --

19 MR. HURST: It's an optional ingredient in claims 47
03:50 20 and 10.

21 THE COURT: Where is it -- it's mentioned in the
22 specification I think.

23 MR. HURST: I'm not going to have that handy.

24 MS. ROYZMAN: I can help.

25 THE COURT: It's in column 8, line 14.

1 MS. ROYZMAN: Yeah. And Your Honor, it's also in
2 column 7, line 63 because it occurs in connection with two
3 embodiments of the invention.

4 THE COURT: Is soy hydrolysate -- would a person
5 ordinarily skilled in the art in 2004 understand soy
6 hydrolysate to be chemically defined?

7 MR. HURST: They would absolutely understand that
8 people were working on accomplishing just that.

9 THE COURT: But it wasn't then?

03:50 10 MR. HURST: Remember --

11 THE COURT: Just here --

12 MR. HURST: The answer is at that point in time it
13 hadn't been done.

14 THE COURT: Okay.

15 MR. HURST: So while we're looking at column 8, and
16 the four ingredients there listed as optional, just optional,
17 three of those are chemically defined, and they can be
18 supplements. And so the reference to supplements, to me,
19 doesn't shed any light on -- doesn't shed by itself any light
03:52 20 on "chemically defined" or "chemically undefined," but when you
21 read the patent specification as a whole, the whole goal here
22 is to make a chemically defined media, cultured, cultured
23 media. That's the whole goal. You're not going to put
24 supplements in there to defeat the goal.

25 So you've got two examples, both examples 1 and 2,

1 it's undisputed between the parties that those examples are
2 chemically defined medium.

3 THE COURT: It says so.

4 MR. HURST: Yeah.

5 THE COURT: What about example 3?

6 MR. HURST: Example 3, I think works if I remember
7 correctly, example 3 takes one of the prior examples and adds
8 to it, yeah. So it would also be chemically defined.

9 THE COURT: Where does it do that?

03:52 10 MR. HURST: It takes the MET 1, it says, "Lactate
11 concentrations at MET 1 media" --

12 THE COURT: What line are you on?

13 MR. HURST: I was looking at the top of example 3.

14 If you take a look at line 30, line 31, it says --

15 THE COURT: Hold on a second.

16 MR. HURST: Sure.

17 THE COURT: Let's see. Column 10, line 44 in the
18 paragraph before the Claim 1 says, "The present invention now
19 being fully described it will be apparent to one of ordinary
03:53 20 skill in the art that many changes and modifications can be
21 made thereto without departing from the spirit or scope of the
22 appended claims." What does that mean?

23 MR. HURST: I would say that when they say, "The
24 present invention has now been fully described," and they
25 describe two examples that both parties agree are chemically

1 defined, that that's consistent with the present invention
2 being a chemically defined cell culture media.

3 THE COURT: But it goes on to say, "It would be
4 apparent to one of ordinary skill in the art that many changes
5 and modifications can be made thereto without departing from
6 the spirit or scope of the appended claims."

7 MR. HURST: I'd emphasize "without departing from the
8 spirit or the scope of the appended claims." The "spirit"
9 being "Our present invention is."

03:54 10 THE COURT: No. I think it's saying, it seems to be
11 saying to me, and I'm not ordinarily skilled in the art, that
12 many changes and modifications can be made to the present
13 invention without departing from the scope of the claim, that
14 there's some flexibility.

15 MR. HURST: No question. There's flexibility in the
16 sense that as long as you're still creating chemically defined
17 cell media culture, you can add chemically defined additions.

18 THE COURT: You're going to tell me again they were
19 trying, but the soy hydrolysate wasn't chemically defined at
03:55 20 this time.

21 MR. HURST: No, but you have to remember the
22 question -- when you're writing a claim, you're writing for the
23 future. And when you cite art in your --

24 THE COURT: I don't think that's right. I think
25 you're writing for a person ordinarily skilled in the art.

1 What would that person at that time understand.

2 Because this goes to -- did I ask you yesterday or
3 today? This goes to my understanding of the purpose of
4 patents. Patents define what's protected. But they're
5 intended to give notice to potential other inventors who might
6 want to compete that you can do this. You can't do this;
7 you're excluded, but you can do that. Strike a balance. No.
8 I would think you have to look at the person of ordinary
9 skilled in the art at the time.

03:56 10 MR. HURST: And I am. And at the time, a person, one
11 of ordinary skill in the art would know for sure that soy
12 hydrolysate could be included if it was chemically defined and
13 not included if it was chemically undefined.

14 THE COURT: I don't know. Is there any evidence that
15 anybody chemically defined the soy in 2004?

16 MR. HURST: Yeah.

17 THE COURT: You said they were trying.

18 MR. HURST: There's literally articles about that
19 subject.

03:56 20 THE COURT: You said they were trying.

21 MR. HURST: Yeah, but that means people know about it.

22 THE COURT: And they know that people are trying.

23 Trying and succeeding are two different things.

24 MR. HURST: The patent lasts for 17 years, so they
25 know, people working on this, they don't want to -- they're

1 including within the scope of their claims. If I'm right that
2 the present invention is chemically defined media cell culture,
3 then that means soy hydrolysate can be -- and it's the only
4 optional ingredient. That optional ingredient can be added
5 throughout the term of the patent as long as it's chemically
6 defined.

7 THE COURT: Go ahead.

8 MR. HURST: So the claims themselves, obviously, they
9 only list chemically defined. When you limit it to 61
03:57 10 ingredients, they're all chemically defined ingredients.

11 Now, let's get to the word "comprising," Your Honor.

12 THE COURT: Okay.

13 MR. HURST: If you go to slide 38, this is the case
14 that I cited earlier. It's Gillette.

15 THE COURT: Hold on a second. Okay. What page?

16 MR. HURST: Page --

17 THE COURT: 1376.

18 MR. HURST: That's right. "The term 'comprising' is
19 not a weasel word with which to abrogate claim limitations, or
03:58 20 to impermissibly expand a claim's scope."

21 THE COURT: Hold on a second. I read that. Go ahead.

22 MR. HURST: In this case the whole patent was -- it's
23 Gillette razors. It was about a three-blade razor, and it used
24 the word "comprising," and the question was, Well, does that
25 mean you can alter the number of blades because it says

1 "comprising"? Adding or subtracting -- or adding I guess
2 another blade. And the Court said, No. "Comprising" can't do
3 that much work. And here, our view is that the word
4 "comprising" can't do so much work that you're literally
5 sweeping in all the problems from the prior art that you say
6 you solved.

7 THE COURT: I'm looking at *Gillette*, which I haven't
8 studied, but the next line says, "The dependent claims
9 themselves demonstrate that the blade unit of the invention
03:59 10 contains only three blades, including a single second blade."
11 Then it says on the next page, 1377, "Specification similarly
12 limits the invention to a blade unit having only three blades."
13 Let me read this.

14 Okay. Go ahead.

15 MR. HURST: So in *Gillette*, they're doing what I'm
16 doing, which is they're saying, Okay, it has the word
17 "comprising" but you can't stop there. You have to look
18 elsewhere to decide whether or not it makes any sense to allow
19 the additions that the patentee is proposing.

04:00 20 THE COURT: The first place the Court looked in
21 *Gillette* was to the other claims. Did the other claims help
22 you here?

23 MR. HURST: I don't think they help us. They also, in
24 my view, don't hurt us. But the specification helps us. Take
25 a look at *Gillette* while you have it. If you go to page 1377

1 the last paragraph on 1377. "We have construed claims to be
2 limited to one type of device where a written description has
3 emphasized features of that device and criticized other similar
4 devises." They cite *SciMed*. There are a lot of cases like
5 that.

6 That's what we have here right? We have here a
7 specification that says, The problem in the prior art is
8 chemically defined. The need is chemically defined. Our
9 present invention is chemically defined. Two examples,
04:02 10 chemically defined title, abstract, chemically defined. And
11 Janssen is in the courtroom now saying, No, no, no. It also
12 includes chemically undefined, and that's what these cases say
13 you ought not be doing.

14 So this is Dr. Wurm. This is at slide 39.

15 THE COURT: Hold on a second. Dr. Wurm is --

16 MR. HURST: The expert witness that Janssen used.

17 THE COURT: Right.

18 MR. HURST: But what he's saying is, "Comprising"
19 means if you want to, you can add serum, you can add animal
04:02 20 serum. But that's literally what the spec says they're trying
21 to overcome. That's what they're saying the problem with the
22 prior art their invention solved. And he's reading the claims
23 to say, yeah, you can toss in bovine syrup and the risk of mad
24 cow disease. That's how he's reading it, and that's how
25 Janssen is reading it.

1 So let's get to Claim 4. I know that's the part
2 that's causing you the most hesitation. So I'm going to slide
3 40.

4 THE COURT: Claim 4. Okay.

5 MR. HURST: The first thing I wanted to note, it says,
6 "optionally adding," "optionally." We cited a case to you --
7 that's the oddest thing in the world. "Optionally" makes it
8 meaningless, right?

9 THE COURT: What case is that?

04:04 10 MR. HURST: We cited -- I'm going to have somebody --
11 I'm going to get the cite for you in a second.

12 THE COURT: All right. Go ahead.

13 MR. HURST: It says it makes the claims undefined.
14 The point is, it's a meaningless thing to say in a claim,
15 because if it's optional, you don't need it and you can still
16 infringe. And if you add it, what's the difference, right?

17 THE COURT: Say that again. I'm not following you.

18 MR. HURST: If it says "optionally adding," that means
19 it's not required to meet the scope of the claims. If so, why
04:04 20 do you include the phrase "optionally added"? It's an oddity.
21 It's an odd thing to be doing.

22 THE COURT: You couldn't say you have the option of
23 adding one of the four things in F in column 12?

24 MR. HURST: You have that option, but say you did none
25 of those things, right, you didn't add anything. You'd still

1 fall within the scope of the claims because of the word
2 "optional." And we cited the case on page 10 of our reply
3 brief.

4 THE COURT: What case is that?

5 MR. HURST: It's *Hockeyline*, Southern District of New
6 York, 2013.

7 THE COURT: *Hockeyline*?

8 MR. HURST: *Hockeyline*.

9 THE COURT: Let me get it. What page?

04:05 10 MR. HURST: Looks like it spills from 5 to 6.

11 THE COURT: 5 to 6.

12 MR. HURST: I think it's really towards the end of the
13 opinion. It's actually --

14 THE COURT: Here.

15 MR. HURST: Very last line.

16 THE COURT: It's on 6, isn't it?

17 MR. HURST: I think the printout I have -- I'm not
18 sure it matches up. It's a Westlaw printout.

19 THE COURT: It says here, "The Court cannot agree with
04:06 20 the plaintiff's reading grammatically the adverb 'optionally'
21 until claim 9 modifies" -- is that what you want me to look
22 at."

23 MR. HURST: The conclusion. "By using this word
24 'optionally.' " "Because there's no way for the public to know
25 the exact bounds of the claimed invention, claim 9 is

1 indefinite." It spills -- literally that's the last sentence.

2 THE COURT: Is that the issue here?

3 MR. HURST: Well, no.

4 THE COURT: Right now you're not arguing that the
5 claim is invalid. You're asking me to define it.

6 MR. HURST: What I'm suggesting, Your Honor, is that
7 it shows that you can practice this invention without -- even
8 this claim -- without soy hydrolysate at all, without any of
9 these things. So it's an odd thing to be putting in here. But
04:07 10 they did put it in there. But maybe the reason they put it in
11 there is optionally. I don't know. It's in this Franek
12 article that we've cited and talked about.

13 THE COURT: Which article?

14 MR. HURST: It's the Franek. It's cited in the
15 patent. It's at the top of column 1 of all their references.
16 But this is what I was talking about. One of ordinary skill in
17 the art, when they read that, they would know about Franek.
18 When they read the optional use of soy hydrolysate --

19 THE COURT: Here. Is that the article that says
04:07 20 they're trying to chemically define the soy?

21 MR. HURST: Yeah. It shows what they're doing.

22 THE COURT: Let me get it.

23 MR. HURST: While you're looking, Your Honor, just to
24 make a --

25 THE COURT: Just wait.

1 MR. HURST: Okay.

2 THE COURT: What's the significance of this article in
3 pertinent part?

4 MR. HURST: So I have some of the parts on slide 41.
5 I can walk you through it, what's happening here.

6 THE COURT: Go ahead.

7 MR. HURST: They talk about the beneficial effect of
8 protein hydrolysates on the growth of animal cell cultures.
9 And it's been known for a long time there's been efforts to try
04:09 10 to define it to try to replace animal serum with all the
11 drawbacks the specification recites.

12 They say, "A substantial drawback of most commercially
13 available crude protein digests is the presence of nonpeptide
14 components of mostly unknown nature." And they talk about a
15 lot of the drawbacks just like the specification does.

16 They say, "Typically, tens of percent" can be of
17 ill-defined character when you're using hydrolysates. They
18 talk about attempts at replacing these crude protein
19 hydrolysates and nutrient medium by defined peptides.

04:09 20 THE COURT: Have been reported several --

21 MR. HURST: Several attempts.

22 THE COURT: -- attempts.

23 MR. HURST: Right.

24 THE COURT: Doesn't that communicate that -- wouldn't
25 that communicate to one ordinarily skilled in the art that

1 there hadn't been any success despite at least a decade or
2 several decades' effort?

3 MR. HURST: And as long as there has been no success,
4 you don't use that optional ingredient. As soon as it is a
5 success, you use that optional ingredient.

6 Here is what they say at the end. Here is what
7 they're doing, Your Honor. I'll explain what this means. But
8 "Resolution of the enzymic hydrolysates of plant proteins by
9 low-pressure liquid chromatography on small-pore size exclusion
04:10 10 matrices is a crucial step toward obtaining peptide fractions
11 of substantially higher quality." And they're talking about
12 what's going on right now to try to make this optional
13 ingredient available.

14 What they're really doing -- what you do is you
15 pulverize the soy protein, okay? And you get -- it's just --
16 it breaks apart into amino acids, vitamins, peptides, okay?
17 What they're doing is they're using chromatography. It's a
18 method of separating individual components, sometimes by size,
19 sometimes by different of their properties. And what they're
04:11 20 saying is, this process might enable you to extract from the
21 mix only what you care about, i.e., defined.

22 THE COURT: Does this article use the term "chemically
23 defined"?

24 MR. HURST: No. But the title says, "Preparation of
25 Defined Peptide Fractions." They're not saying they've done

1 it. Here, "Defined peptides. Attempts at replacing crude
2 protein hydrolysate in nutrient media by defined peptides have
3 been reported several decades ago." It's been going on for a
4 while. If it hasn't been accomplished you don't use the
5 optional ingredient.

6 THE COURT: This says you can use the optional
7 ingredient.

8 MR. HURST: Not if I'm right --

9 THE COURT: Not if you're right, but I'm trying to
04:12 10 determine if you're right.

11 MR. HURST: I think that assumes the answer.

12 THE COURT: I think you're assuming the answer. I
13 understand your argument. Move on.

14 MR. HURST: Okay. Here is the last thing. Maybe I
15 should have started with this because I'm not -- there's a huge
16 logical problem, huge logical problem with saying you can add
17 chemically undefined soy hydrolysate into this patent. Huge
18 logical problem, okay?

19 Here is why. If you made soy hydrolysate, you just
04:12 20 pulverized it, without knowing what amino acids are in there,
21 what vitamins are in there, and you tossed it into the cell
22 culture media from Claim 1, you could no longer determine the
23 concentrations. Claim 1 requires -- Your Honor, there's a
24 logical problem. Claim 1 requires specific concentrations
25 sometimes, Your Honor, to the fifth decimal point. That's how

1 precise, to the fifth decimal point.

2 And Claim 1 includes -- there's only 21 amino acids in
3 the world, right? It includes amino acids. It includes
4 vitamins. If you attempted to add undefined soy hydrolysate,
5 you would be varying the concentrations. And because you don't
6 know the amount or what you're adding, you would have no way of
7 knowing whether you met the concentrations in Claim 1. So
8 there's a logical problem. Does that make sense?

9 THE COURT: No.

04:13 10 MR. HURST: Let me try again.

11 THE COURT: No. If you're making a cake and you put
12 ingredients in in a specific amount -- if you want to make this
13 particular chocolate cake, you put each of the ingredients in
14 in this specific amount. Then maybe you say it's optional to
15 put in red coloring or whatever, white. I don't know.
16 Something that would change the color of chocolate, not brown.
17 I don't think that would change the amounts of the essential
18 ingredients that you put in. You would have just added some
19 other ingredient.

04:14 20 MR. HURST: The point that I didn't make clearly
21 enough maybe is the ingredients you're adding with soy
22 hydrolysate, they match up inevitably with the ingredients that
23 are set forth in Claim 1.

24 THE COURT: What do you mean "match up"?

25 MR. HURST: I'm going to give you an example.

1 THE COURT: You're telling me all these things. Maybe
2 the claims are invalid.

3 MR. HURST: That wouldn't make it invalid. I think
4 that would prove my point that soy hydrolysate, to the extent
5 it's going to be added, has to be chemically defined.

6 THE COURT: All right. I understand the argument.

7 MR. HURST: Just give me -- it will take one second,
8 and I know it's late. I'm just trying to give you an example.

9 THE COURT: Not as late as it's going to get. Go
04:15 10 ahead.

11 MR. HURST: Here is one. So L --

12 THE COURT: What are you reading from?

13 MR. HURST: Claim 1.

14 THE COURT: From Claim 1?

15 MR. HURST: Yeah. If you look at column 11.

16 THE COURT: Hold on a second. I have to find my copy.
17 Claim 1. Go ahead.

18 MR. HURST: So Claim 1 has arginine HCL at 200 to
19 5,000 milligrams, right?

04:16 20 THE COURT: Where is that? What column?

21 MR. HURST: Column 11, ten lines down, just giving one
22 example.

23 THE COURT: Go ahead.

24 MR. HURST: So now it has to be within that range. If
25 you pulverized the soy hydrolysate and you had no idea what you

1 were adding was a bunch of undefined components, you wouldn't
2 have any way of knowing whether you were inside or outside that
3 concentration. So logically then the soy hydrolysate that is
4 being active in Claim 4 optionally has to be chemically
5 defined, in our view. In any event, soy hydrolysate is not a
6 protein, so it doesn't address the protein issue. It's a
7 nonprotein.

8 THE COURT: Is it your contention that there has to be
9 no protein?

04:17 10 MR. HURST: That is our contention. That's part of
11 the "chemically defined" definition. Here is what I would --

12 THE COURT: What slide is that?

13 MR. HURST: I was actually just going to sum up, Your
14 Honor.

15 THE COURT: Okay.

16 MR. HURST: Sum up, on slide 21, I'll pick one of the
17 large charts. Your Honor, I just got that *Gilead* note quote
18 that I gave you before. I'm being told it was actually a quote
19 from the dissent, but *Gillette* is quoting a majority, *Spectrum*
04:17 20 *Intern* --

21 THE COURT: Hold on a second. What page of *Gillette*?

22 MR. HURST: What page do I cite in *Gillette* or
23 *Spectrum*?

24 THE COURT: I don't know what language you're citing.

25 MR. HURST: Where "'Comprising' can't be a weasel

1 word." Unfortunately --

2 THE COURT: That's the dissent?

3 MR. HURST: Unfortunately, yeah. The *Gillette* quote
4 from was from a dissent. But *Gillette* is quoting from a
5 majority in *Spectrum Intern v. Sterilite Corp.*, 164 F.3d 1372
6 at 1376. But it's the same concept.

7 THE COURT: Hold on just one second.

8 MR. HURST: Sure.

9 THE COURT: Let me get *Spectrum*.

04:19 10 This is a case where *Spectrum* argued one thing to get
11 the patent and then took a different position with regard to
12 infringement? This is in the context of contrary prosecution
13 history.

14 MR. HURST: I think that might be right, Your Honor.

15 THE COURT: I also see on their -- I don't see the
16 "weasel word" discussion.

17 MR. HURST: Page 1380, Your Honor.

18 THE COURT: 1380?

19 MR. HURST: Did I say the wrong page? I apologize if
04:21 20 I did. "'Comprising' is not a weasel word."

21 THE COURT: There it is, yeah. Okay.

22 MR. HURST: Let me find just the -- in terms of --
23 maybe what I just want to emphasize in terms of -- if I were to
24 put a balance -- I understand and I can hear Your Honor that
25 this soy hydrolysate is causing you some hesitation, the

1 optional ingredient in Claim 4. But let's balance that against
2 all the present invention case law and the very clear present
3 invention statements in the claim. You couple that together --

4 THE COURT: What are you looking at, 21?

5 MR. HURST: I'm looking at 29.

6 THE COURT: What slide are you looking at?

7 MR. HURST: 29. So my thought would be to balance the
8 optional ingredient as construed by the art saying that they're
9 working on defined soy hydrolysates, in particular, all the
04:22 10 present invention case law and the clear present invention
11 statements here would say that the invention is chemically
12 defined and therefore shouldn't be chemically undefined.

13 Couple that with the --

14 THE COURT: Which slide has the case law?

15 MR. HURST: I went through the case law earlier.

16 THE COURT: Which slide was that on?

17 MR. HURST: Let me say -- slide 13. I'm sorry.

18 That's wrong. Slide 18, slide 19, and we also cited in our
19 footnote in page 6, note 2, page 6, note 2, of a reply brief
04:23 20 where we have a string cite of cases relying on present
21 invention.

22 THE COURT: Okay. Thank you.

23 MR. HURST: Couple that with -- the optional
24 ingredient in Claim 4 against the present invention statements
25 in the present invention case law. Just add on to the scale

1 title and abstract, which says, Listen, our invention is
2 chemically defined, not chemically undefined.

3 Place that in the context of the need in the art,
4 where they say, Look at all the disadvantages in the art, and
5 what do you need? You need a chemically defined media culture,
6 and they say that's the need right before they describe their
7 invention in two examples, both of which are chemically defined
8 media culture, cell culture media.

9 So all of that points in our view in only one
04:24 10 direction, which is "chemically defined" not "chemically
11 undefined." And if Janssen were correct, Your Honor, you could
12 literally put bovine syrup in Claim 1. And that's what they
13 said don't do. If they're right, bovine syrup with those 61
14 ingredient infringes Claim 1.

15 THE COURT: But even if you need the 61 -- I don't
16 know. It sounds to me like you're asking me to define the
17 invention, not the term.

18 Okay. I mean, I've heard you. I'm going to continue
19 to think about it.

04:24 20 MR. HURST: Sure, sure. I don't think I am, though.

21 THE COURT: All right.

22 MR. HURST: I'm saying you're adding -- it's just like
23 all these cases. It's not every kind of the broad word. It's
24 the kind they say they invented. It's as simple as that. It's
25 "chemically defined cell culture media."

1 THE COURT: How do you want me to construe this claim?
2 Have you abandoned the alternative construction "nutritive
3 media free of all proteins for culturing eukaryotic cells" that
4 your expert said was wrong?

5 MR. HURST: Well, in his defense --

6 THE COURT: Just tell me what your construction is.

7 MR. HURST: Number one, "chemically defined media."
8 That's what we want. We want "Chemically defined media," and
9 all we did was add to that.

04:25 10 THE COURT: Here, look. First of all -- and I must
11 have discussed this with you previously. My strong preference
12 is for doing *Markman* constructions in the context of motions
13 for summary judgment because it gets very abstract. You agreed
14 that it would be useful in this case, helpful in this case, to
15 do it or try to do it now. And because I recognize the urgency
16 of this and the new statutory regime, a lot of money is
17 involved. It's important to the parties. I'll try.

18 But to put a new construction in a late brief is not
19 appropriate. And ordinarily, if it came in a reply brief in an
04:26 20 ordinary case, I wouldn't even consider it. But I need to know
21 because now I'm -- I need to know what I'm being asked. And
22 this is a question I asked you at the outset, because it frames
23 everything. Am I correct that you're asking me to construe
24 "cell culture media" to mean "chemically defined media, i.e.,
25 media compositions containing only known chemical compounds

1 that are free of all proteins, even those not of animal origin,
2 such as recombinant proteins optimized for biopharmaceutical
3 production"?

4 MR. HURST: I am.

5 THE COURT: Okay. Then I'll decide whether -- based
6 on what I know now, that's the correct construction. And this
7 is -- I asked Ms. Royzman this. I don't know if I asked you or
8 whether you responded to it also. But am I correct that, you
9 know, *Markman* constructions can evolve or change in the course
04:27 10 of a case?

11 MR. HURST: It can.

12 THE COURT: So I'll do the best I can now.

13 MR. HURST: Just to add one quick thing, Your Honor.
14 What we're saying is "chemically defined media," everything
15 after "i.e.," that's a quote from their definition. So it
16 looks long, but we just pulled their definition from the
17 specification into that, that's that parenthetical. And the
18 reason for the alternative construction was only to try to
19 eliminate the soy hydrolysate optional ingredient issue because
04:28 20 it's not a protein. And I understand Your Honor's comments,
21 but our key thing is "chemically defined." That's our key
22 thing. "Chemically defined." Is it chemically defined or
23 chemically undefined. That is the core issue.

24 THE COURT: Well, look, I've spent a lot of time
25 preparing for this, and I focused on the two proposed

1 constructions. That was developed by an infinite number of
2 lawyers apparently on each side. So that's what I'm going to
3 decide. Actually, I asked you about the alternative,
4 "nutritive media free of all proteins for culturing eukaryotic
5 cells." Where did you first introduce that proposed
6 construction?

7 MR. HURST: It was in our reply brief. We had two
8 briefs. In our second brief.

9 THE COURT: A, that's not appropriate. B, that's the
04:29 10 one your expert in his deposition said was wrong, correct?

11 MR. HURST: Because it didn't have the word
12 "chemically defined." And I understand why he did that, but he
13 did make that mistake. And it wasn't a happy moment, Your
14 Honor. I saw you smiling.

15 THE COURT: Because it didn't have --

16 MR. HURST: So he read it. He thought it was
17 Janssen's because it didn't have "chemically defined," which is
18 the core issue --

19 THE COURT: I see.

04:29 20 MR. HURST: He made a mistake.

21 THE COURT: Oh, he just took that position because he
22 thought it was Janssen's? In other words, you pay him, and
23 he'll take whatever position he thinks will help you. That's
24 what you're arguing.

25 MR. HURST: No, I'm not, Your Honor.

1 THE COURT: That's what you're communicating to me
2 shows the wisdom of *Phillips*. Okay.

3 MR. HURST: Just please, just one second. The whole
4 issue turns --

5 THE COURT: If we get --

6 MR. HURST: He read this without "chemically defined"
7 and said to himself, Well, that's not what I've been proving --

8 THE COURT: How do you know what he said to himself?
9 Did you ask him why he said that in the deposition?

04:30 10 MR. HURST: We know what he did.

11 THE COURT: Did you ask him?

12 MR. HURST: Yeah. It was explained on the record. He
13 wasn't paying attention. He thought it must have been
14 Janssen's, not ours.

15 THE COURT: He said that?

16 MR. HURST: Yeah, that's what he said. He read it
17 quickly. He wasn't paying attention. This was ours. He saw
18 this -- look, I'm not making excuses.

19 THE COURT: If we have a trial -- here. It's too
04:30 20 late. It's too late.

21 Okay. Let me put it this way. This confirms my view
22 developed over 31 years in dealing with patent cases that the
23 Federal Circuit is certainly right in discounting and saying we
24 should discount the expert testimony that is prepared for
25 litigation purposes because it may suffer from bias. That's

1 just an observation. All right.

2 MR. HURST: Judge --

3 THE COURT: You're not finished yet?

4 MR. HURST: Just one thing. Just so sometimes -- I do
5 a lot of these *Markman* hearings. Sometimes the outside makes
6 points you address or the judge makes points you address. I
7 really want to emphasize our key issue is, is it chemically
8 defined or not chemically undefined.

9 THE COURT: If it's that simple, why didn't you say
04:31 10 that at the outset of all your briefs?

11 MR. HURST: We did. This is the definition of
12 "chemically defined" in the spec. We just took the definition
13 of "chemically defined" from the spec. That's the core issue
14 between the parties.

15 THE COURT: They said that would be optimal, ideal.

16 All right. Let me ask the plaintiff, how do you
17 distinguish *Gillette*?

18 MS. ROYZMAN: I'm sorry, Your Honor, *Gillette* was the
19 comprising case --

04:31 20 THE COURT: The razor blade case.

21 MS. ROYZMAN: Razor blade case.

22 THE COURT: Mr. Hurst says this case is like *Gillette*.

23 MS. ROYZMAN: Then he pointed out -- hold on, Your
24 Honor. So we read through all of the comprising cases that
25 defendants cited, and I think, as Mr. Hurst pointed out,

1 Gillette cited *Spectrum* or something like that. And these
2 cases are very easy to distinguish for the reasons that Your
3 Honor actually started discussing while looking through, I
4 believe, *Spectrum*.

5 These are cases where you have a prosecution history
6 disclaimer or you have a disclaimer of some kind. And at that
7 point, if you have a disclaimer or you relinquish something,
8 you can't use "comprising" to put it back in. But that's not
9 our situation at all. In our claims, "comprising" serves an
04:33 10 essential and necessary function because they are disclosed
11 embodiments which are chemically undefined.

12 THE COURT: Where are "disclosed embodiments that are
13 chemically undefined" in your patent?

14 MS. ROYZMAN: Okay. So I think I may have left my
15 patent -- okay. Those are the two that we discussed in columns
16 7 and 8. So in column 7, Your Honor, it begins with line 53
17 and goes through lines 83 at slide 61 and 62 of our
18 presentation. And these are embodiments of the invention, as
19 cell culture media. It explicitly --

04:34 20 THE COURT: These are the references to the soy?

21 MS. ROYZMAN: Yes, absolutely. And as Mr. Hurst had
22 to acknowledge and as his expert acknowledged at his
23 deposition, to this day, it's impossible to define soy
24 hydrolysate. It is chemically undefined. There's nothing in
25 this patent whatsoever that says soy hydrolysate is somehow

1 defined, because that wouldn't even make any sense. Nothing
2 like that existed in 2004, and nothing like that exists today.

3 THE COURT: Are there other points that Mr. Hurst made
4 that you'd like to address?

5 MS. ROYZMAN: Mr. Hurst made a number of statements
6 about present invention, and I will just address those very
7 quickly. And he also pointed Your Honor to a whole footnote of
8 present invention case law, and all of those cases are in
9 opposite. And let me just explain why.

04:35 10 So slide 54, please. So Mr. Hurst focused you on two
11 present invention statements or two invention statements. And
12 they're in our slide 54. I had referred you to them as well.
13 And these are not statements that even say the present
14 invention is a chemically defined media because that just
15 wouldn't be true. They talk about that it relates to
16 chemically defined media compositions. It provides
17 compositions, and then you can use those 61 ingredients with
18 other chemically defined ingredients or undefined ingredients.
19 And over and over in the patent -- could I have slide 55,
04:36 20 please -- talks about the invention being a cell culture media.
21 The invention also --

22 THE COURT: I'm sorry. This is 55?

23 MS. ROYZMAN: Yes. And this is four of the
24 statements. There are seven such statements. I believe
25 they're all cited in our answer answering brief, along with the

1 relevant case law.

2 But the point is that over and over we say -- and now
3 in connection with cell culture media, that the invention is
4 just the cell culture media, soluble composition for making a
5 cell culture media. And of course it makes sense that we say
6 that because we disclose and we claim chemically undefined
7 embodiments, that constructions being advocated by Mr. Hurst
8 are contrary to established claim construction principles.

9 THE COURT: I guess at the moment -- it's possible I'm
04:37 10 wrong. I'm due to be. I come back to it. I'm being asked to
11 define "cell culture media."

12 MS. ROYZMAN: Yes.

13 THE COURT: If there's something that requires the
14 invention to be chemically defined, in my present conception
15 it's not that term. It's something else, like, it has to
16 comprise these ingredients, and, you know, if a jury at some
17 point in these proportions were persuaded that if you throw soy
18 in there, it will affect the concentrations of the other
19 things, as Mr. Hurst was arguing, based on -- as Mr. Hurst
04:38 20 arguing, maybe there will a problem with the invention. But I
21 think my task right now is more limited to just, what does
22 "cell culture media" mean? That's all I was asked to do.
23 That's what I'm prepared to do.

24 MS. ROYZMAN: No. Your Honor, we completely agree.

25 It's just that defendants are arguing that "cell culture media"

1 has this definition and that these present invention statements
2 somehow demand that. Could I have the next slide? The law is
3 just to the contrary.

4 THE COURT: What's the next slide?

5 MS. ROYZMAN: 56. It's slide 56, Your Honor. It's
6 the *Absolute Software* case. And I don't actually think there
7 are any invention statements in Mr. Hurst's favor. But even if
8 there were, unless the statements are uniform and unless
9 there's no intrinsic evidence to the contrary, those statements
04:39 10 are not limiting. That's just simply the law and their
11 statements, statement after statement, that just say this
12 invention is a composition for making a cell culture media.
13 That's the law. And Mr. Hurst ignores each one of those
14 statements.

15 THE COURT: All right. It's 20 of 5:00. I'm going to
16 hold you hostage here for a while because I may be able to
17 decide this this afternoon, and then I'll let you know what
18 time to come back tomorrow. Court is in recess is.

19 (Recess taken 4:39 p.m. to 5:14 p.m.)

05:13 20 THE COURT: Once again, I'm going to decide this
21 matter orally and construe the term "cell culture media" as
22 used in Claim 1 particularly of the '083 patent. I'm doing
23 this because there's urgency to having the matter decided in
24 view of the relatively new regime for litigating issues
25 concerning biosimilar drugs. I'm doing it because I'm immersed

1 in the issue. The transcript, again, will be a record of the
2 decision. I may convert it into a more formal memorandum and
3 order.

4 In addition, as the parties recognize, a *Markman*
5 construction of a claim can evolve or change in the course of a
6 case. The parties have each asked me to do this claim
7 construction before we get to summary judgment, if summary
8 judgment is ever appropriate. I'm trying to be of service.
9 But it's conceivable, as more work is done, the claim
05:15 10 construction could evolve or change. I don't anticipate that
11 now, however.

12 I have studied this deeply based on the submissions.
13 I construe the term "cell culture media" as used in Claim 1 in
14 patent number 7,598,083, the '083 patent, to mean nutritive
15 media for culturing cells. This is the construction advocated
16 by the plaintiffs, Janssen Biotech and New York University. It
17 is, I find, the plain meaning of the term for people skilled in
18 the art. In reaching this conclusion, I've applied the
19 standards for claim construction in the relevant cases that
05:16 20 include but are by no means limited to *Phillips*, 415 F.3d 1303
21 at 1312 to 19, *Renishaw*, 158 F.3d 1243 at 1248 to 50, *Comark*,
22 156 F.3d 1182 at 1186 to 87, *Thorner*, 669 F.3d 1362 to 67. All
23 of those are Federal Circuit cases. I've also considered the
24 key cases cited today, particularly in the arguments. In
25 addition, I've taken the approach I described through *Markman*

1 in *Biogen v. Berlex*, 113 F. Supp. 2d, 77 at 95 to 96.

2 Claim 1 of the '083 patent is "a soluble composition
3 suitable for producing a final volume of cell culture media
4 wherein the composition comprises the following components in
5 the following amounts per liter of the final volume of cell
6 culture media." This sentence is followed by a list of 61
7 chemicals in certain defined concentration ranges for each.

8 The plaintiffs and defendants propose constructions of
9 the term "cell culture media" in their opening briefs as
05:18 10 follows:

11 Janssen asserts that "cell culture media" has its
12 plain and ordinary meaning to those skilled in the art; that
13 is, a nutritive media for culturing cells. Until its reply
14 brief at least, the defendant asserted that "cell culture
15 media" means chemically defined media, i.e. media compositions
16 containing only known chemical compounds and are free of all
17 proteins, even those not of animal origin, such as recombinant
18 proteins, optimized for biopharmaceutical use.

19 In their reply brief, which is an utterly
05:19 20 inappropriate time for a party to add a new argument or change
21 its argument and which the jurisprudence indicates is a basis
22 for disregarding the argument, the defendants asserted that
23 "cell culture media" should be construed to mean nutritive
24 media free of all proteins for culturing eukaryotic cells.
25 This is a proposed construction that was not in the prehearing

1 statements required by our local rules and my orders.

2 In essence, the defendants argue that "cell culture
3 media" should be construed to, one, exclude media containing
4 any proteins like defendants' media; and two, include only
5 media that are optimized for biopharmaceutical production.
6 That's the assertion in the defendants' opening brief at page
7 15. In particular, they argue that the specification indicates
8 that "cell culture media" must be construed to mean chemically
9 defined media and that the specification of the '083 expressly
05:20 10 defines "chemically defined" as media composition containing
11 only known chemical compounds and are free of all protein, even
12 those not of animal origin, such as recombinant proteins,
13 language that comes from column 1, lines 46 to 49 of the
14 Background of Invention in the specification.

15 In the alternative, defendants argue that the term
16 should be construed of being free of all proteins, regardless
17 of whether the media must also be chemically defined.
18 Plaintiffs argue that no construction is necessary because the
19 meaning of "cell culture media" is obvious and universally
05:21 20 understood. In the alternative, they argue that it should be
21 construed according to the plain and ordinary meaning, which is
22 nutritive media for culturing cells. As indicated earlier, I
23 find that the plaintiffs' proposed construction is correct.

24 With regard to the standard and process for construing
25 the term "cell culture media," I've done the following:

1 I've decided how a person ordinarily skilled in the
2 art would understand the claim term "cell culture media" in
3 Claim 1 of the '083 patent. As instructed by *Phillips* at 1312
4 and 1313, I have started with the claim term and considered its
5 ordinary and customary meaning. I've also considered the
6 specification and the fact that the parties agree there isn't
7 any prosecution history -- well, I've also considered the
8 specification as a person of ordinary skill in the art would.
9 I've considered the prosecution history, but as the parties
05:23 10 seem to agree, it does not have direct relevance to the
11 construction of the claim now at issue.

12 I've also considered whether the inventor clearly
13 expressed an intent to be its own lexicographer, and to give a
14 term in the patent a unique meaning different from what would
15 commonly be understood by a person skilled in the art, as
16 *Thorner* instructs at 669 F.3d 1362. In addition, I've
17 considered whether the patentee disavowed part of the otherwise
18 broad scope of the claim, Claim 1.

19 Finally, I've considered extrinsic evidence concerning
05:24 20 relevant scientific principles that are, and were in 2004, when
21 the patent was issued, available to persons skilled in the art,
22 including technical dictionaries and treatises, as *Phillips* at
23 1314 and 1318 and *Renishaw*, 158 F.3d at 1250 indicate a court
24 may and should do.

25 I have the discretion to consider expert testimony on

1 the meaning of the term. However, I understand, as the Federal
2 Circuit indicated in *Phillips* at 1318, it should be discounted
3 if it's clearly at odds with the claim construction mandated by
4 the language of the claim, the written description of the
5 prosecution history, and it should also be discounted to the
6 extent the Court discerns that it was prepared for litigation
7 and therefore suffers from bias.

8 As I mentioned earlier, there's a small Federal
9 Judicial Center volume, Anatomy of a Patent Case, that in
05:25 10 Chapter 9, Section 5B at 101 makes the same point about
11 essentially encouraging courts to be skeptical about expert
12 testimony prepared for litigation. What I've been educated to
13 understand so far about defendants' expert indicates that that
14 skepticism is well founded in this case.

15 I find that in this case the inventor did not act as
16 its own lexicographer concerning the term "cell culture media."
17 To act as its own lexicographer, the patentee must clearly set
18 forth a definition of the disputed claim term other than its
19 plain and ordinary meaning. It is not enough for the patentee
05:26 20 to simply disclose a single embodiment or use a word in the
21 same manner in all embodiments, as the Federal Circuit said in
22 *Thorner*, 669 F.3d at 1365.

23 I also find that the inventor did not disavow the
24 usual broad meaning of "cell culture media" in the
25 specification. After explaining in *Thorner* the high standard

1 for finding that a patentee acted as its own lexicographer, the
2 Federal Circuit wrote at 1366, "The standard for disavowal of
3 claim scope is similarly exacting. Where the specification
4 makes clear that the invention does not include a particular
5 feature, that feature is deemed to be outside the reach of the
6 claims of the patent, even though the language of the claims
7 read without reference to the specification might be considered
8 broad enough to encompass the feature in question.

9
05:27 10 "The patentee may demonstrate intent to deviate from
11 the ordinary and custom meaning of a claim term by including in
12 the specification expressions of manifest exclusion or
restriction representing a clear disavowal of the claim term."

13
14 The Federal Circuit also addressed this in *Luminara*
15 and said, "Absent lexicography or disavowal, we do not depart
16 from the plain meaning of the claims," citing *Thorner*. To act
17 as a lexicographer, a patentee must clearly set forth a
18 definition of the disputed claim term and clearly express an
19 intent to redefine the term. Similarly, disavowal requires
05:28 20 that the specification or prosecution history make clear that
the invention does not include a particular feature. While
21 such disavowal can occur either explicitly or implicitly, it
22 must be clear and unmistakable. We have found disavowal or
23 disclaimer based on clear and unmistakable statements by the
24 patentee that limit the claims, such as "The present invention
25 includes," or "The present invention is," or "All embodiments

1 of the present invention are."

2 I do not, however, discern the required clear
3 disavowal of the usual claim scope in the specification of the
4 '083 patent.

5 The term "culture medium" has a definite meaning that
6 would be familiar to a person skilled in the art for the
7 purpose of this case. The Oxford English Dictionary, which the
8 plaintiff submitted as Exhibit 6 to docket number 149-7,
9 defines "culture medium" as "a nutrient liquid or solid in or
05:29 10 on which microorganisms, cells, et cetera, are cultivated."
11 There are similar definitions in the other lay dictionaries
12 submitted by plaintiffs as Exhibits 3, 4 and 5.

13 More significantly, the Oxford Dictionary of
14 Biochemistry and Molecular Biology, a technical dictionary,
15 defines "culture medium" as "any nutrient medium that is
16 designed to support the growth or maintenance of a culture."
17 That is in evidence in docket number 149-3 as Exhibit 2.
18 *Phillips*, 415 F.3d at 1318 notes the particular value of
19 technical dictionaries in determining what a term would mean to
05:30 20 the person ordinarily skilled in the art.

21 The term "cell culture medium" has also been
22 interpreted in many cases. In *SkinMedica*, 727 F.3d. 1187 at
23 1190, it was construed to mean "an artificial environment, such
24 as a liquid, that is outside the body, *in vitro*, and supplies
25 the components necessary to meet the nutritional needs required

1 to grow cells." *SkinMedica* is a 2013 Federal Circuit case.

2 In 2000, in *Biogen v. Berlex*, 113 F. Supp. 2d 77 at
3 83, I, without controversy in that case, defined a culture
4 medium as "a solution that contains the nutrients required for
5 maintenance and growth of the cell." Therefore, "absent a
6 special and particular definition created by the patent
7 applicant, the terms in the claim, Claim 1, must be given their
8 ordinary and accustomed meaning," as the Federal Circuit said
9 in *Renishaw*, 158 F.3d at 1249.

05:32 10 In Claim 1, the term "cell culture media" is
11 unmodified. Accordingly, as the Federal Circuit also said in
12 *Renishaw*, quoting *Specially Composites*, 845 F.2d 981 at 987,
13 "Unless the specification requires a limitation, that
14 limitation should not be read from the specification into the
15 claim."

16 In this case I recognize that the specification
17 includes or the patent includes the following: The title is
18 "Chemically Defined Media Compositions." Under "Field of
19 Invention," the specification states, "The present invention
05:33 20 relates to chemically defined media compositions for the
21 culture of eukaryotic cells." As I will reiterate, it doesn't
22 say, "The present invention is" or "only is chemically defined
23 media compositions."

24 Under "Field of Invention," the patent states -- I'm
25 sorry. So as I said it -- under "Field of Invention," the

1 patent states, "The present invention relates to chemically
2 defined media compositions for the culture of eukaryotic
3 cells." It doesn't say, "The present intention is." Nor does
4 it there or elsewhere, I believe, say, "The present invention
5 includes," or "All embodiments of the present invention are,"
6 as was the situation in the cases cited in *Luminara*, where
7 disavowal of broad claim language was found by virtue of the
8 specification.

9 In addition, in describing the desirability of a cell
05:35 10 culture media that will not become contaminated, the background
11 of invention states, in part, "Ideally, such media are
12 chemically defined such that the media compositions contain
13 only known chemical compounds and are free of all proteins,
14 even those not of animal origin, such as recombinant proteins."
15 "Ideally," commonly, colloquially, means preferably, or,
16 according to the Macmillan dictionary, "In the best possible
17 way." This language in the "Background of the Invention"
18 section does not suggest, let alone state, that the cell
19 culture media being patented must be free of all proteins.
05:36 20 Rather it addresses the type of medium that would be best and
21 therefore preferable.

22 Moreover, this statement relates to the background of
23 the invention claimed. It is not specific to the invention
24 claimed. In addition, it does not address the term "cell
25 culture media." The detailed description of the invention

1 states that, "The present invention provides chemical
2 compositions useful in the culture of eukaryotic cells."
3 That's column 4, lines 30 to 31. This, like the language just
4 discussed, addresses the nature of the invention, not the
5 meaning of the term "cell culture media," which is only part of
6 the language in Claim 1 that describes the invention claim.

7 Moreover, that statement should not be viewed in
8 isolation. I also recognize that the two examples -- or two
9 examples in the patent at least, perhaps all three, are
05:37 10 embodiments involving chemically defined culture media.
11 However, as the plaintiff has argued, "because claim terms are
12 normally used consistently throughout the patent, the usage of
13 the term in one claim can often illuminate the meaning of the
14 same term in other claims," as the Federal Circuit said in
15 *Phillips* at 1314.

16 In Claim 4 of the '083, the invention described is "a
17 composition comprising a cell culture media made by steps
18 comprising," and then F says, "optionally adding at least one
19 substance selected from a group consisting of, among other
05:39 20 things, soy hydrolysate." "Soy hydrolysate," as defendant, I
21 believe, acknowledges and as the record indicates, is not
22 chemically defined. There may have been long efforts to
23 chemically define "soy hydrolysate." There's no report that
24 they've succeeded, and certainly as of 2004, they had not.

25 In Celltrion's claim construction reply brief at 11,

1 it writes, "To be sure, 'soy hydrolysate' typically is not
2 chemically defined." Therefore, that Claim 4 and I think also
3 Claim 10, which references soy hydrolysate, would communicate
4 to a person reasonably skilled in the art that the invention
5 had to include the chemicals listed in Claim 1 in the
6 proportions stated. The invention could also include elements
7 that are chemically undefined, such as soy hydrolysate.

8 At times the specification uses the term "cell culture
9 media" without reference to it being chemically defined.

05:42 10 Examples of this are in slide 55 that Janssen presented today,
11 and its Exhibit E patent specification says, among other
12 things, "One aspect of the invention is a soluble composition
13 suitable for producing cell culture media." Elsewhere it says,
14 "The invention also provides compositions comprising cell
15 culture media." Elsewhere it states, "In one embodiment, the
16 invention provides a composition comprising of cell culture
17 medium made by steps comprising certain things." In addition,
18 the patent states in another embodiment, "The invention
19 provides a composition comprising a cell culture media made by
05:43 20 certain steps."

21 So the Federal Circuit in *Absolute Software*, 659 F.3d
22 1121 at 1136 said, "We have found the use of the phrase
23 'present invention' or 'this invention' is not always so
24 limiting," as the defendant would contend here about similar
25 but not the same language, "such as where the reference is to a

1 certain limitation as being the invention are not uniform or
2 other portions of the intrinsic evidence do not support
3 applying the limitation to the entire patent." At best, I'm
4 not even finding this, there is inconsistency in the
5 specification.

6 As the Federal Circuit said in *Thorner*, 669 F.3d 1365
7 to 66, "It is not enough for a patentee to simply disclose a
8 single embodiment or use a word in the same manner in all
9 embodiments. The patentee must clearly express an intent to
05:44 10 redefine the term at issue to serve as its own lexicographer or
11 disavow the broad claim language." In this case, Janssen has
12 done less than that.

13 As described earlier, the term "cell culture media"
14 alone would be clear to a person, that is, clearly understood
15 by a person ordinarily skilled in the art. When read in the
16 context of the rest of Claim 1, the specification would not
17 communicate to such a person that the term "cell culture media"
18 means a composition containing known chemical compounds and are
19 free of all proteins, as the defendant in part contends. Nor
05:45 20 is the defendants' alternative construction correct. Nutritive
21 media free of all proteins for culturing new eukaryotic cells
22 was said to be wrong by the defendants' expert himself.

23 As explained earlier, the invention claimed in Claim 1
24 is a soluble composition suitable for producing a final volume
25 of the cell culture media wherein the composition comprises the

1 following components in the following amounts per liter of the
2 final volume of cell culture media. It then lists 61 chemicals
3 in certain concentration ranges.

4 If anything -- and this is an open question -- but if
5 anything, it would be the language about what the composition
6 comprises that would require that the cell culture media
7 include chemical components. However, even that language would
8 not communicate to a person ordinarily skilled in the art that
9 the composition could not also include proteins or matters of
05:47 10 undefined chemical composition, like the soy.

11 As the Federal Circuit wrote in *Genentech*,
12 "'Comprising' is a term of art used in claim language which
13 means that the named elements are essential, but other elements
14 may be added and still form a construct within the scope of the
15 claim." That's 112 F.3d 495 at 501. Chisum on Patents, Volume
16 3-8, Section 806 at 1B2A, advises that the same definition of
17 "comprising" is appropriate.

18 Now this is not a case such as *Spectrum*, 164 F.3d 1372
19 at 1379, 80 where the word "comprising" was argued in a weasely
05:48 20 way to try to contradict a position taken in the prosecution
21 history in the prosecution of the patent.

22 As I indicated earlier, the specification in claim
23 language would tell a person reasonably skilled in the art that
24 the claimed invention could include "soy hydrolysate," which is
25 also indicated earlier as known to be chemically undefined.

1 In construing "cell culture media" to mean nutritive
2 media for culturing cells, I'm not crediting the opinion of the
3 defendants' expert. To the extent it helps the defendants, it
4 is an opinion generated for litigation that appears to be an
5 example of the litigation bias warned about in *Phillips* at
6 1318. In any event, it's inconsistent with the written record
7 of the '083 patent. It is the public record of the patent that
8 described the scope of the '083 invention for those skilled in
9 the art and provided notice of what was protected and what
05:49 10 alternatives would be permitted. I've relied on that record.

11 Sorry to make you sit here so long, but I need to
12 explain my reasoning and my results. Okay. I still would like
13 to rule on the reexamination motion for summary judgment on the
14 '471, and I have to hear you and decide the requests for an
15 expedited trial.

16 Is there anything else that should be on the agenda?

17 MR. HURST: I think we're going to ask for a 54(b)
18 judgment on the '471 patent.

19 THE COURT: So 54(b), you want me to enter judgment so
05:50 20 it can be immediately appealed?

21 MR. HURST: That's right, Your Honor.

22 THE COURT: When are you going to do that?

23 MR. HURST: I was just going to do it orally tomorrow.

24 THE COURT: Well, why don't you write something. Why
25 don't you confer and see whether you have a -- is that

1 something that the plaintiffs likely is going to oppose?

2 MR. DISKANT: Frankly, I'd like to hear you --

3 THE COURT: What's that?

4 MR. DISKANT: I'd like to hear what Your Honor does on
5 the reexam before my client is in a position to reach a
6 conclusion on that.

7 THE COURT: All right. If you want to make a
8 motion -- are you admitted pro hac vice?

9 MR. HURST: I am.

05:51 10 THE COURT: So you said you know the local rules.
11 Under local Rule 7.1B -- Mr. Kelly will tell you -- 7.1B, you
12 can't file any motion without conferring with your adversary.
13 So you'll have time to do that.

14 MR. HURST: Thank you, Your Honor.

15 THE COURT: Okay. This may be a good candidate, but I
16 haven't thought about it. If you disagree, I'll have to listen
17 to both sides. You'll have to brief it -- or maybe you'll have
18 to brief it.

19 MR. DISKANT: I think those are the only two items on
05:52 20 the agenda, Your Honor.

21 THE COURT: Well, everything takes me longer to do
22 than I think it is. So you should come back at 1:00 tomorrow,
23 too. It will give me the morning to look more closely at the
24 reexamination issue and my other cases perhaps.

25 MR. DISKANT: Your Honor, I'm sorry. I've been

1 reminded that there's also the stipulation --

2 THE COURT: About consolidating?

3 MR. DISKANT: Right, but that's stipulated to.

4 THE COURT: Right, right. Good. And I raised that
5 yesterday, and I asked you to remind me.

6 MR. DISKANT: I was reminded by Ms. Royzman.

7 THE COURT: Okay. All right. Well, it's up to you,
8 but now you know more than you knew yesterday. So I encourage
9 you to keep talking and to let me know if you've reached any
05:53 10 agreements that mean I don't have to continue to work on this.

11 Court is in recess.

12 THE COURT: Again, with particular great thanks to the
13 court reporter, as well as the rest of my staff. I forgot to
14 do what I conventionally do, and that is to order the parties
15 to give the stenographer a dictionary of all the technical
16 terms. But you'd be amazed by how quickly she came up with the
17 "soy" whatever. But I appreciate everybody working so hard
18 with me on this. Court is in recess.

19 (Recess taken 5:53 p.m.)

20

21

22

23

24

25

1
2 CERTIFICATE OF OFFICIAL REPORTER
3

4 I, Kelly Mortellite, Registered Merit Reporter
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6 District Court for the District of Massachusetts, do hereby
7 certify that pursuant to Section 753, Title 28, United States
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9 stenographically reported proceedings held in the
10 above-entitled matter and that the transcript page format is in
11 conformance with the regulations of the Judicial Conference of
12 the United States.

13 Dated this 24th day of August, 2016.
14

15 /s/ Kelly Mortellite
16 _____
17

18 Kelly Mortellite, RMR, CRR
19 Official Court Reporter
20
21
22
23
24
25

EXHIBIT 11

From: Andrew Chalson
Sent: Friday, March 24, 2017 1:10 PM
To: 'Warner, Kevin E.'; Nick Cerrito
Cc: Park, Sam; Reig, Eimeric; Lin, Sharon; 'sjcorr@jonesday.com'; 'cmiller@jonesday.com'; Catherine Mattes; Jeffrey Matthews; Ross Misskelley; Eric Stops; Robert Wilson
Subject: RE: Celgene v Actavis (Abraxane) - motion scheduling

Kevin,

As we discussed on Wednesday, Celgene does not object to Actavis submitting a proper reply in and of itself. Rather, as we discussed, we are concerned about the schedule in this case, and the timing of your briefing (including the requested reply) only heightens that concern, as does your refusal to discuss the impact on the schedule at this time. Nevertheless, if you insist, Celgene will not object to a 5-page double-spaced reply on April 19th that is properly limited to the issues raised in Celgene's opposition.

Andrew Chalson
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From: Warner, Kevin E. [mailto:KWarner@winston.com]
Sent: Thursday, March 23, 2017 3:33 PM
To: Andrew Chalson <andrewchalson@quinnmanuel.com>; Nick Cerrito <nickcerrito@quinnmanuel.com>
Cc: Park, Sam <SPark@winston.com>; Reig, Eimeric <EReigPlessis@winston.com>; Lin, Sharon <SLin@winston.com>; 'sjcorr@jonesday.com' <sjcorr@jonesday.com>; 'cmiller@jonesday.com' <cmiller@jonesday.com>; Catherine Mattes <catherinemattes@quinnmanuel.com>; Jeffrey Matthews <jeffreymatthews@quinnmanuel.com>; Ross Misskelley <crossmisskelley@quinnmanuel.com>; Eric Stops <ericstops@quinnmanuel.com>; Robert Wilson <robertwilson@quinnmanuel.com>; Warner, Kevin E. <KWarner@winston.com>
Subject: RE: Celgene v Actavis (Abraxane) - motion scheduling

Andrew,
It looks like we're in agreement on 3/29 and 4/12, and we also will not object to Celgene responding exclusively to the amended portions of our contentions within a reasonable time if amendment is allowed. However, Actavis maintains that it should have a reply opportunity in the briefing because Actavis is the party requesting relief. If you still disagree, we can submit a proposed schedule noting that disagreement along with a cover letter asking the Court to decide whether it will allow us the requested reply. Let me know your position and we will draft a joint letter to the Court.

Your other comments are irrelevant side issues that we will not address except to say that we disagree Actavis is seeking "that much additional time," as you say, in this schedule. We also disagree that there is any need to modify any

part of the fact discovery schedule now. If you make a request to do so, we will address the request at that time as appropriate.

Kevin Warner

Winston & Strawn LLP

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From: Andrew Chalson [<mailto:andrewchalson@quinnmanuel.com>]

Sent: Wednesday, March 22, 2017 12:29 PM

To: Warner, Kevin E. <KWarner@winston.com>; Nick Cerrito <nickcerrito@quinnmanuel.com>

Cc: Park, Sam <SPark@winston.com>; Reig, Eimeric <EReigPlessis@winston.com>; Lin, Sharon <SLin@winston.com>; 'sjcorr@jonesday.com' <sjcorr@jonesday.com>; 'cmiller@jonesday.com' <cmiller@jonesday.com>; Catherine Mattes <catherinemattes@quinnmanuel.com>; Jeffrey Matthews <jeffreymatthews@quinnmanuel.com>; Ross Misskelley <crossmisskelley@quinnmanuel.com>; Eric Stops <ericstops@quinnmanuel.com>; Robert Wilson <robertwilson@quinnmanuel.com>

Subject: RE: Celgene v Actavis (Abraxane) - motion scheduling

Kevin,

We are surprised that Actavis requires that much additional time to prepare a motion that it's been contemplating for at least the past several weeks, but we are willing to work with you to expedite this process. Specifically, we are willing to accept your proposed dates and page limits/formatting for the opening (3/29) and responsive (4/12) briefs, but we propose to end the briefing there so that Judge Falk has as much time as possible to render a decision.

Also, as you previously stated when the parties met and conferred, it is our understanding that, if Actavis prevails on any portion of its motion, it will not object to providing Celgene with a reasonable time to respond to any amended contentions.

Finally, Celgene reserves the right to seek an appropriate extension of fact discovery should Actavis prevail on any portion of its motion to provide sufficient time to respond to, and to take discovery pertaining to, any amended contentions.

Please confirm the above or let us know if you'd like to discuss.

Thanks,

Andrew Chalson

Partner

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From: Warner, Kevin E. [<mailto:KWarner@winston.com>]

Sent: Wednesday, March 22, 2017 10:40 AM

To: Nick Cerrito <nickcerrito@quinnmanuel.com>; Andrew Chalson <andrewchalson@quinnmanuel.com>

Cc: Park, Sam <SPark@winston.com>; Reig, Eimeric <EReigPlessis@winston.com>; Lin, Sharon <SLin@winston.com>;

'sjcorr@jonesday.com' <sjcorr@jonesday.com>; 'cmiller@jonesday.com' <cmiller@jonesday.com>; Warner, Kevin E.

<KWarner@winston.com>

Subject: RE: Celgene v Actavis (Abraxane) - motion scheduling

Counsel,

Can you please confirm today your agreement with this schedule? Thanks,

Kevin Warner

Winston & Strawn LLP

D: +1 (312) 558-5852

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From: Warner, Kevin E.

Sent: Monday, March 20, 2017 1:13 PM

To: Nick Cerrito (NickCerrito@quinnmanuel.com) <NickCerrito@quinnmanuel.com>; Andrew Chalson (andrewchalson@quinnmanuel.com) <andrewchalson@quinnmanuel.com>

Cc: Warner, Kevin E. <KWarner@winston.com>; Park, Sam <SPark@winston.com>; Reig, Eimeric <EReigPlessis@winston.com>; Lin, Sharon <SLin@winston.com>

Subject: Celgene v Actavis (Abraxane) - motion scheduling

Nick and Andrew,

Following up on our call with Judge Falk last week about Actavis's request for leave to serve amended invalidity contentions, we propose the following schedule:

3/29: Actavis files opening letter brief in support of its position, 10 page limit (double-spaced, per the Court's request).

4/12: Plaintiffs file responsive letter brief, 10 page limit

4/19: Actavis files letter brief in reply to Plaintiffs' response, 5 page limit.

Let us know if you agree and we will prepare an appropriate proposed order for submission to the Court. I'm available to discuss. Thanks,

Kevin Warner

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